Cancer Council NSW
Ethics Committee

CONFLICT OF INTEREST

Policy and Guidelines

Approved by the Board of Cancer Council NSW
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Background
The Cancer Council NSW Ethics Committee (‘the Ethics Committee’) is a committee that
reports to the Board of Cancer Council NSW. The Ethics Committee is responsible for
providing ethical assessment of proposals to use health data able to identify individuals that
is held by Cancer Council NSW for research or other purposes. It also provides ethical
assessment of proposals for research involving human participants conducted by staff of
Cancer Council NSW.

In assessing the ethical acceptability of these proposals, the Ethics Committee examines the
extent of their compliance with NHMRC’s guidelines for Human Research Ethics
Committees as stated in the NHMRC National Statement on Ethical Conduct in Human
Research, 2007, the National Statement) and Cancer Council NSW’s Privacy policy.

The Guiding Principles outlined in the Charter of the Ethics Committee highlight that:
- A properly constituted Ethics Committee must assess all research activity undertaken
  at Cancer Council NSW involving humans and/or requiring access to health data able
to identify individuals held by Cancer Council NSW.
- There will be a transparent and systematic process for ensuring that research
  proposals meet appropriate ethical standards.
- The Ethics Committee will in all aspects operate consistent with the National
  Statement.

One in three people in Australia will be diagnosed with cancer, and therefore it is to be
expected that research into cancer, including research into cancer epidemiology and public
health implications, will be a major focus in the research arena. There is significant
collaboration between the limited number of cancer research institutions in Australia.
Consequently, it is recognised that in order to ensure compliance with the National
Statement, for the composition of an Ethics Committee, and that ethical review of research
proposals involves experienced researchers who are familiar with the type of research under
review, there will be times when a member of the Ethics Committee is closely affiliated with
the research being reviewed or has a connection that could be considered influential.

In addition, Cancer Council NSW’s internal Cancer Research Division employs researchers
who actively compete for research funding, ensuring that Cancer Council NSW is involved in
ongoing, leading-edge research and thus better able to maintain a strategic national and
international health research presence. It is critical that this expertise is available and worth
preserving (Canadian Institutes of Health Research 2005). However, this structure,
combined with NHMRC requirements for an appropriately constituted Ethics Committee, that
could leave Cancer Council NSW open to criticism that conflicts of interest may arise.

Conflict of Interest
A conflict of interest is a situation where an individual, or the organisation he or she
represents or has an interest in, has a real, potential or perceived, direct or indirect
competing interest with Cancer Council NSW’s activities. This competing interest may result
in the individual, or others related to them, or entities in which they have an interest, being in
a position to benefit from the situation, or in Cancer Council NSW being prevented from
achieving a result which would be in the best interests of the public and Cancer Council
NSW. Conflict under this policy is interpreted broadly (Canadian Institutes of Health Research 2003).

More specifically, in relation to the Ethics Committee, conflict of interest means a situation where the private or employment interests of an Ethics Committee member, or other persons participating in the work of the Committee, influence or compromise the performance of that person in the conduct of their Ethics Committee activities, including developing Committee policy, making decisions as to the ethical acceptability of a proposed project, or disclosing research outcomes related to ethics. Apparent conflicts may undermine trust and be as damaging as an actual conflict (Australian National University 2002b).

There are many possible sources of conflicts of interest. Conflicts can arise from commercial interests; ethical, political or religious views; or personal relationships. The ‘benefits’ that may be obtained from a situation where there is a conflict of interest may be tangible (e.g., approval for a project in which a person has an interest) or intangible (e.g., the achievement of the good opinion or status due to influence of another person with a conflict of interest being exercised). The potential for a conflict does not necessarily imply wrongdoing on anyone's part.

The most common conflicts are those arising from commercial interests and close personal relationships (Australian National University 2002a). The following covers situations that are broader than those likely to be apparent with the work of the Ethics Committee but may impact upon them; hence they are included in these Guidelines:

**Financial conflicts of interest may arise:**

- Where an Ethics Committee member, or other person participating in the work of the Ethics Committee, also has an employment or personal interest (or a person with whom the member has a close personal relationship has an employment or personal interest) in research that may be considered by the Ethics Committee.
- From an Ethics Committee member, or other person participating in the work of the Ethics Committee, having financial involvement in an external company that may have an interest in the research being ethically approved and therefore allowed to proceed under Cancer Council NSW's auspices, such that the member’s activities with the Ethics Committee could lead to professional, personal or economic gain, thereby providing incentive to bias the decision making of the Ethics Committee in relation to ethics approval and any advice and/or conditions that may be provided on the design, conduct or reporting of research.

**Where a close personal relationship exists:**

- The relationship between the parties should not affect the interests of Cancer Council NSW, the work of the Ethics Committee, other parties or the research being conducted.
- Because the effects on other people are frequently not apparent to the persons involved in a close personal relationship, anyone with such an involvement should be attentive to the feelings of colleagues and to the potential conflicts of interest that may be involved.
  - One party should not be the direct supervisor of the other.
One party should not be involved in decision-making or procedures leading to the ethics approval of research.

One party should not have access to the personal files of the other (Australian National University 2002a).

**Other conflicts that may arise:**

- Remunerated or honorary positions and other connections with educational institutions which may give rise to a conflict of interest, including relevant external government or public committees, such as other research councils, charities, Government Departments, professional bodies and training organisations.
- Prolonged absence - a staff member having a commitment outside the Ethics Committee that involves frequent or prolonged absence from Ethics Committee meetings.
- Gifts or offers of gifts of significant value, other than official gifts, and ex gratia payments (Australian National University 2002a).

Both the membership of the Ethics Committee and the guiding principles, while being supported by the Board and the Ethics Committee, pose challenges in their application. As discussed above the expertise required for the appropriate assessment and review of research necessarily requires the active engagement of cancer research experts. In Australia, this pool is limited and inevitably the people concerned have developed collegial links even if they reside and work in different organisations and jurisdictions. Members of the Ethics Committee who are researchers, no matter how ethical their conduct may be, could be perceived as having a potential interest in many of the projects reviewed by the Ethics Committee, merely because of their career choice and work.

The objectives of the Ethics Committee also conceal inherent ethical risks relating to potential for real or perceived conflicts of interest to arise for Ethics Committee members. The following table outlines some of these risks against the objectives:
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<th>Objective</th>
<th>Potential for Real or Perceived Conflicts of Interest to Arise</th>
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| Ensure that all CCNSW research activity involving humans complies with National Health and Medical Research Council (NHMRC) guidelines for Human Research Ethics Committees as stated in the *National Statement on Ethical Conduct in Human Research*, 2007, and the Cancer Council’s Privacy Management Plan. Protection of the rights and welfare, including privacy and confidentiality, of participants and/or their health records involved either directly or indirectly in the proposals considered by the Ethics Committee. Promote ethical standards of human research and information privacy by provision of guidance to investigators. Facilitate ethical research through efficient and effective review processes. Ensure that all releases of health data held at Cancer Council NSW are in accordance with the NHMRC *National Statement on Ethical Conduct in Human Research*, 2007, and relevant privacy legislation. | • *Policies and procedures may be oriented to aspects of cancer research aligned to particular interests and engagement of members of the Ethics Committee.*  
• *Policies and procedures may have inbuilt disincentives to the facilitation of cancer research that is outside the particular interests and engagement of members of the Ethics Committee.*  
• *Being in a position to influence access to subject records or databases such that the research outcomes could be affected.*  
• *The imposition of processes or policies from external organisations which could compromise the ethical standards of the research.*  
• *The robustness of procedures for the independent review of projects such as:*  
  o *The mechanisms for ensuring transparency and accountability of all processes and each decision point.*  
  o *The selection process for independent external expert reviewers.*  
  o *Processes for ensuring independence, identifying and disclosing conflicts of interest in relation to independent external expert reviewers.*  
  o *The decision making discretions of the Ethics Committee in relation to recommendations made by independent external expert reviewers.*  
  o *The existence and application of appeal procedures for dealing with complaints of conflicts of interest.* |
The increasing complexity of conflicts, including those of personal relationships and financial gain from outside commercial activities and infringement of intellectual property rights, make clear principles and procedures essential. The provisions of State and Commonwealth legislation, organisational and professional codes of conduct and ethics and policy require all Ethics Committee members to behave in good faith, avoid conflicts of interest and act with propriety when making decisions about ethical matters.

Related to this is the common law obligation of confidentiality. All Ethics Committee members must ensure that sensitive and confidential matters relating to the ethical review of research or administration of Cancer Council NSW and the Ethics Committee are not improperly disclosed, either internally or externally.

**Principles – Conflict of Interest**

It is the policy of Cancer Council NSW that its staff, and others acting on its behalf, conduct themselves according to the principles and procedures outlined in this document; avoid ethical, legal, financial, or other conflicts of interest; and ensure that their activities and interests do not conflict with their obligations to any research funded or conducted by Cancer Council NSW, or their welfare. This includes Ethics Committee members.

In meeting the objectives of the Ethics Committee, members shall:

**Ethical Standards**

Act with honesty and uphold the highest ethical standards in order to honour and enhance public confidence in Cancer Council NSW's ability to act in the public interest and for long-term public good.

**Public Scrutiny**

Perform their Ethics Committee responsibilities and arrange their private affairs in a manner that will bear the closest public scrutiny, an obligation that is not necessarily fully discharged by simply acting within the law.

**Decision Making**

In fulfilling their Ethics Committee duties and responsibilities, make decisions in the interest of Cancer Council NSW, with a view to the public interest, and with regard to the merits of each case.

**Private and Employment Interests**

Disclose fully any employment or private interests that could be affected by actions of Cancer Council NSW or that could put ethical practice at risk.

**Public Interest**

Recognise the potential that their employment or private affairs could cause real, potential or apparent conflicts of interest to arise in relation to their Ethics Committee obligations; and if such a conflict does arise between the employment or private interests of an individual and the official Committee duties and responsibilities of that individual, the conflict shall be disclosed and all steps taken to resolve it, minimising the impact on the interests of Cancer Council NSW.
**Gifts and Benefits**
Not solicit or accept transfer of economic benefit, other than incidental gifts, customary hospitality, or other benefits of nominal value from persons, groups or organizations having, or likely to have, dealings with Cancer Council NSW unless the transfer is pursuant to an enforceable contract or property right of Ethics Committee member.

**Preferential Treatment**
Not step out of their official Committee roles or misuse confidential Committee documents or business to assist private entities or persons in their dealings with Cancer Council NSW where this would result in preferential treatment to any person or organisation.

**Insider Information**
Not knowingly take advantage of, or benefit from, material information that is not generally available to the public that is obtained in the course of their official Committee duties and responsibilities.

**Property of Cancer Council NSW**
Not directly or indirectly use, or allow the use of property of Cancer Council NSW of any kind, for anything other than officially approved activities.

**Post Ethics Committee Activity**
Not act, after they leave the Ethics Committee, in such a manner as to take improper advantage of their previous office (Canadian Institutes of Health Research 2003).

**Guidelines**
Cancer Council NSW requires that conflicts are managed according to the following steps when they arise or can be imputed to arise:
1. disclose always;
2. manage the conflict where appropriate; and
3. prohibit any activity when necessary to protect the public interest or the interests of Cancer Council and the Ethics Committee (Australian National University 2002a).

Disclosure by an Ethics Committee member or staff member must be made when there is potential for conflict, or the perception that a conflict may exist. Disclosure must be full and prompt, and made in writing. In the case of close personal relationships, either party to the relationship can make a disclosure. The primary obligation is to notify, in advance, any potential conflict. Written approval should be obtained before any commitment is made that might involve a conflict (Australian National University 2002a).

Not providing notification of a potential conflict could be regarded as a serious matter, may affect the person’s ongoing involvement with the Ethics Committee and in extreme cases may warrant legal action. A third party, being aware of a potential or actual conflict of interest, should also report it.

There may be occasions when a conflict becomes known after the fact of a decision or determination. In these cases, as soon as the conflict becomes evident, it must be reported...
to the Ethics Committee Chairperson. Cancer Council NSW may decide to investigate the circumstances of the decision or determination, including whether a different decision or determination ought to be made. Cancer Council NSW may also determine that an investigation should be undertaken to determine whether other action is required.

**PRIVACY**
Cancer Council NSW recognises that the disclosure by an individual of a potential conflict could involve the disclosure of personal information. Cancer Council NSW adheres to information privacy principles and will treat information provided in accordance with these principles. Any individual who is concerned about the potential ramifications of disclosing particular information may raise their concerns directly with the Chief Executive Officer (CEO) of Cancer Council NSW or their delegate, particularly if they feel it is inappropriate to disclose such information to the Ethics Committee Chairperson. The CEO or their delegate will determine how and to whom any information is subsequently disclosed bearing in mind the requirements of this policy and the privacy of the individual concerned (Australian National University 2002a).

In order to comply with this policy, members of the Ethics Committee:

**In the development of policy and procedures**
Must as individuals and as a Committee, be aware of their potential to influence the substance of policy and procedures developed for the purposes of meeting the Ethics Committee’s objectives; and take active steps to test any Committee decision and output for such bias.

**In giving ethical approval on behalf of Cancer Council NSW for research projects**
The presumption is that the recommendations of any external expert reviewers of research projects will be accepted by the Ethics Committee as they are recommended.

Should the Ethics Committee have strong reasons not to accept the recommendations of any external expert reviewers regarding ethical approval, the CEO or their delegate must be formally notified and review the Ethics Committee’s reasons for taking the view they have.

Where any recommendations made by external expert reviewers vary from an evaluation by the Ethics Committee, and the Ethics Committee is unwilling to adopt the recommendations, the Ethics Committee must demonstrate that their decision is made without bias and the justification for the decision should be provided in writing for formal review by the CEO or their delegate.

**If involved with research projects making application to Cancer Council NSW for ethical approval**
May be part of a research team applying to Cancer Council NSW for the ethical approval of a research project.
Must disclose their involvement to the Chair of the Ethics Committee if they are part of the research team or in any situation that could be perceived as creating a conflict of interest when seeking ethics approval for a research project sponsored by their organisation.

Must remove themselves from all evaluation and decisions or recommendations for ethics approval undertaken by the Ethics Committee when it includes a research project in which they are involved.

Disclosure Procedures
The Chair of the Ethics Committee is responsible and accountable to the Board of Cancer Council NSW for monitoring the exclusion of the Committee members in the decision-making processes when a disclosure of interests or a complaint of a conflict of interest is made.

Disclosure
Disclosure of a conflict of interest, whether real, potential or apparent, must take place as soon as the individual becomes aware of the conflict.

This may be, for example, in the case of a research project at a meeting when an individual becomes aware that a research project is being proposed or considered; at the first opportunity after an individual becomes interested in an existing or proposed research project; or at the first possible moment when they become involved with Ethics Committee and a research project pre-exists.

The member will then withdraw from the meeting during any Ethics Committee discussion or consideration of the matter relevant to the conflict of interest.

The member will not participate in the discussions and will not be entitled to vote in any decision with respect to any matter relevant to the conflict of interest.

The Committee may, at its discretion, request such information as it deems fit in relation to the matter relevant to the conflict of interest.

Notice
The person making the disclosure should do so: either in the ‘Declaration of Interests Register’ if present at the Committee Meeting; via noting in person at the meeting; or by notifying the Secretariat prior to the Committee meeting.

Details of the declaration of interest with respect to any disclosure will be documented formally in the minutes of the Committee meeting with any discussion or determinations of Committee.

Any times the member making the disclosure leaves and returns to the meeting will also be minuted.
Confidential Notice
In the event that the matter to be disclosed is of a confidential or sensitive nature that would cause undue prejudice through open disclosure, then such matters may be disclosed in confidence to the Chair of the Ethics Committee.

If, after receiving such disclosure the Chair determines that such matters, in the discretion of the Chair, are not of a confidential or sensitive nature or that the principles or interests of Cancer Council NSW would not be fulfilled without full and open disclosure, then the Chair shall notify the disclosing individual of same and give such individual the opportunity to make such full disclosure.

If the affected individual fails to make such disclosure, it shall then be considered a breach of this policy.

Final Determination
Cancer Council NSW, or its delegate, shall determine in each case whether or not a disclosed interest is acceptable and may continue. The criteria for acceptability may vary and may include, without limit, those principles considered relevant by Cancer Council NSW.

Remedy
Where a disclosed interest is determined to be unacceptable by Cancer Council NSW, they shall make a determination that protects the public interest and the interests of Cancer Council NSW, such determination to be made by the Board or their delegate.

Reservation of Right
Where an individual fails to disclose a conflict or an interest according to this policy or according to other laws or regulations in NSW, Cancer Council NSW reserves all rights which it may have to deal with the situation or conflict and individual involved.

Consequences
Failure to comply with these policies may lead to removal from the position the individual holds on the Ethics Committee and Cancer Council NSW.

Annual Reporting
Cancer Council NSW will include a Conflict of Interest statement in the Annual Report each year outlining any relevant matters that have arisen in the Ethics Committee during the reporting year.

The Conflict of Interest Report will include:
- A brief statement outlining the nature of the conflict of interest or perceived conflict of interest that arose;
- The number of times that it arose; and
- How the conflicts of interest were managed.
References


