Cancer Council NSW Submission to the
Strategic Review of Health and Medical Research in Australia

Background about Cancer Council NSW

The mission of the Cancer Council NSW is to defeat cancer through engaging the community. A key strategic priority for Cancer Council NSW is to drive major advances in research, ensuring no cancer is ignored.

Cancer Council NSW is almost entirely community funded, with 96% of our income coming directly from the community and investments. Fundraising remains our primary source of income to preserve our independence, and a strong investment strategy provides the underpinning for our future ambitions. Cancer Council takes a comprehensive approach to our mission, and is not limited to a single type of cancer, funding program, product or approach in cancer control. The landscape of knowledge and opportunity in cancer changes continually, and so too does our approach and portfolio of research programs.

Cancer Council NSW is the largest funder of cancer research in the not-for-profit sector in the state of NSW. In 2010/11, we invested $16.1 million (12% up on 2009/10) through our internal and external research programs.

Our goal is to fund world-class, groundbreaking research to cover all aspects of cancer control (prevention, diagnosis, treatment and survivorship); drive major advances in research; and ensure no cancer is ignored. We have committed considerable funding into high-mortality and high impact cancers that were traditionally underfunded in the research area (eg brain and pancreatic cancer).

Cancer Council has structured its research into two areas –external/extra-mural and internal – both of which complement each other and extend our capability and capacity.

This submission from Cancer Council NSW focuses on three of the Panel's questions:

- How might health and medical research be best managed and funded in Australia? (Terms of Reference 2, 3 and 7)
- What are the health and medical research strategic directions and priorities and how might we meet them? (Terms of Reference 5, 12 and 13)
- How can we optimise translation of health and medical research into better health and wellbeing? (Terms of Reference 4, 8, 9, 10 and 11)

How might health and medical research be best managed and funded in Australia? (Terms of Reference 2, 3 and 7)

General Feedback

Cancer Council NSW believes that health and medical research funding should be better segmented into meaningful groups. For example, laboratory medical research has different dynamics, needs, drivers from population and clinical research. Basic research and pre-clinical trials have been mainly used as the basis and paradigm for NHMRC grant funding priorities with less tailoring to the requirements for epidemiological research.

Cancer Council agrees that consideration of alternative and innovative funding models is essential for a thriving research culture in Australia. An exploration of social impact bonds may be a way of mobilising community financing for high value population research projects. It would be useful to explore if there are any opportunities to create a pool of funds that will stimulate early engagement of venture capitalists. In general an approach which generates incentives rather than attempts detailed system management is likely to be more rewarding.

There is potential for the private sector to play a more productive role in research. Given the concentration of pathology, imaging, and much procedural work in the private sector, this seems a missed opportunity. As so much of the patient pathway is now catered for outside traditional public hospitals, this setting is critical for studies and linking them into a research framework seems imperative. For example the national bowel cancer screening program generates assessments among private gastroenterologists in bowel cancer and pre-cancer, and in Barrett's Oesophagus and gastro-oesophageal reflux disease; and a range of other chronic disease conditions.

***What are the health and medical research strategic directions and priorities and how might we meet them?* (Terms of Reference 5, 12 and 13)**
How can we optimise translation of health and medical research into better health and wellbeing? (Terms of Reference 4, 8, 9, 10 and 11)

Importance of large epidemiological studies

The growing and ageing population in Australia will result in a much greater health care burden from cancer and chronic diseases. A greater research emphasis must now be placed on ways to better understand the underlying factors that contribute to the progression of chronic diseases like cancer. To this end, two key resources in this challenge, large epidemiological studies such as population cohort studies or large case-control studies and their associated biobanks, must be strategically developed within Australia not only for domestic benefits, but also to allow our health and medical research sector to remain internationally competitive and collaborative.

Large epidemiological studies are essential to understand the exposures and risk factors for improving the detection, prevention, diagnosis, treatment, and prognosis of chronic diseases. One need only look at the plethora of findings in breast, prostate, and bowel cancer published through the European Prevention into Cancer (EPIC) cohort study to appreciate the power of such studies. However, long-term funding is a challenge for many of these large epidemiological studies. Government funding is required not only for maintaining the quality of the current studies, but also to allow for future expansion of these studies. Population health studies are all too often short-sightedly viewed as a finite resource. Indeed, a negligible percentage of the annual NHMRC budget could likely double the size of all population studies in Australia. A key point of difference achievable with Australian epidemiological studies is the ability for record linkage which makes them an even more valuable resource to support.

We ask the Review Committee to recommend:

- Long-term funding commitment for large-scale epidemiological studies
- Strategic promotion of ongoing expansion of these studies (data and/or biospecimens)

Biobanking

Traditionally, many population studies have been limited to epidemiological research and produce limited, if any, biological research output. However, the genomic, proteomic, metabolomic and related bioinformatics revolution in recent years has exponentially improved our understanding of the links between basic and clinical science. Realising this opportunity requires large numbers of biospecimens to provide the required power for ground-breaking study – this is where biobanks become crucial. Instead of multiple studies over time, biobanks allow researchers to acquire thousands of disease-specific biological samples and linked data within weeks. Given the appreciable time taken to accumulate large (i.e. measured in the thousands) collections of biospecimens, biobanks promise to save many years in financial and infrastructure investment and fast-track the transition from benchtop to bedside. For example, Cancer Council NSW has recently analysed 35 different human papilloma virus (HPV) serological markers and their association with cancer of the oesophagus[1], this is the largest study on oesophageal cancer in the world. This would not have been possible without collaboration between key international groups who held onto blood samples from previous studies to investigate promising hypotheses like these.

Increasing numbers of researchers are at a loss about what to do with their 'leftover blood specimens' once a project/ program grant is finished. Freezers storing leftover biospecimens require maintenance and rent far beyond the life of a 3 to 5 year grant.

The majority of Australian biobanks however, are solely tissue-based, have poor linkage to medical data and very limited linkage to lifestyle data, are too small to be high-quality research-effective, and/or have not been designed as a truly open source of access. Indeed, many of these issues have been recognised by the NHMRC review (and workshops) into biobanking and have resulted in the subsequent cessation of enabling grant funding to these biobanks. This strategy appears to have largely been deployed to drive the NHMRC strategy for a more large-scale, centralised (hub and spokes), and collaborative biobank network in Australia. This attitude is mirrored internationally with the most effective biobanks operating as large consortia to maximise effective use of their resource. Many projects are publishing based on samples sizes of about 50,000 participants. To be internationally competitive in biobanking, size matters. But size must not lead to poor quality, a common concern amongst researchers regarding domestic biobank operations. A government-led certification of all Australian biobanking operations would help to standardise operational quality and improve researcher confidence by ensuring each resource is fit-for-purpose.

In biobanking, high quality means high technology and sophisticated automation procedures, and hence funding becomes of primary concern.

The future of population health and biobanking would be best served by strategizing investment in the development of large-scale population biobanks, or a consolidated hub and spoke operation. One example of a large-scale operation that would be ideal for a biobanking component would be the NSW 45 and Up Study that already has data on over 267,000 participants, and proposes to collect blood for a large subset of these participants. As an adjunct to the 45 and Up Study, Cancer Council NSW is strategically investing in an 'all cancer' case-control study and biobank (The CLEAR Study). Such studies provide early access to questionnaire information and biobanked samples, and will provide early results that can be followed up later in cohort studies.

A key governmental strategy to ensure the effective use of funding would be to prioritise the development of 'one-stop shop' biobanks that provide researchers with a single interface for

[1] Sitas F, Egger S, Urban MI et al. InterSCOPE study: Associations between esophageal squamous cell carcinoma and human papillomavirus serological markers. J Natl Cancer Inst. 2012 Jan 18;104(2):147-58. Epub 2012 Jan 6

all their biospecimen and data linkage needs. At present, many researchers must unnecessarily go through multiple institutional ethics committees and other processes to access linked biospecimens. Large-scale biobank collections providing open access to a selection of biological samples linked to well-annotated questionnaire and/or medical data offer the possibility to maintain high standards of governance and operational integrity. Compared to smaller single-focus population biobanks, large combined operations would allow a far greater reach of investigation without the bureaucracy, and thereby allow meaningful collaboration with international players.

Such a move would not only redirect the lost investment from poorly managed biobanks over previous years, but help to revive our national intellectual property and improve health care in a technologically savvy manner (as noted by the Cutler review[2]). It would be in the government's interest to commission an in-depth assessment of public benefits from biobanking, with a focus on robust empirical outcomes.

The limiting barrier to the longevity of population biobanking in Australia is of course a lack of funding, but more specifically, sustainable funding. Although start-up capital maybe secured through government, operational expenses often drive biobanks to failure. This may be because the resource is not used. With both data-only population cohort studies and biobanks, government strategy should be focussed on ways to encourage self-sustaining funding through incentive policies which promote user-provider relationships that are mutually beneficial. One example may be enhanced research funding (biobank costs only) for continued medical research institute-biobank projects (based on study power). Such incentives may have the dual benefits of promoting biobank self-sustainability and optimising data and biospecimen usage.

Industry partnerships in research are vitally important. However, many pharmaceutical companies are attracted overseas (often to Asia) due to cheaper research economics. Admittedly, whilst the pharmaceutical industry's hesitancy to publish findings needs addressing, such partnerships offer significant enhancements in research quality and scale. Indeed, it is often these relationships that lead to commercial discoveries and whilst commerce may be seen by some in a negative light, it remains a key strategy for translating important research outcomes into improved healthcare. One method maybe subsidising large-scale private-public project costs. Also, in relation to infrastructure and start-up costs, increasing the tax write-off may make funding research more attractive to venture capitalists. There are many permutations to consider, though the imperative strategy should always be to assist the self-sustainability of biobanking and similar research ventures.

We ask the Review Committee to recommend:

- Commissioning an in-depth assessment of public benefits from biobanking, focussed on robust empirical outcomes.
- Government-led certification of all Australian biobanking operations to ensure each resource is fit-for-purpose.
- Establish a 'hub and spokes' biobanking network within Australia to coordinate and optimise all biobanking resources.
- Prioritise funding to large-scale biobanks that provide a single interface for all researcher data and biospecimen needs.
- Develop policies that strongly encourage continued partnerships between users (industry in particular) and biobanks, aimed at producing high quality research.

[2] Ref: Cutler T. *Venturous Australia - building strength in innovation, 2008,* Department of Industry, Innovation, Science, Research, and Tertiary Education

Ethics considerations

Apart from strategic investment considerations, Cancer Council believes that the current framework of ethics in Australia should be reviewed. Despite the earnest attempts by initiatives such as the Harmonization of Multi-centre Ethical Review (HOMER), ethics application processes across Australia, particularly when involving multiple institutions, are falling short of the ideal. Human Research Ethics Committees (HRECs) are poorly harmonised and often prolong or prevent projects based on application decisions that are subject to little accountability. For example, in developing a recent report of a national linkage study of Australian Broadcasting Corporation staff records to the national cancer statistics clearing house, the ethics application process alone took nine months to complete 10 separate ethics applications at a cost in excess of $100,000.

A major strategic consideration by government should be the increased implementation of HREC harmonisation (especially where state-owned health administrative data sets, including cancer registries, are involved), and the development of an independent ethics appeals panel and/or audit process.

We ask the Review Committee to recommend:

- Prioritising the harmonisation of Human Research Ethics Committees
- Establishing an independent ethics appeals panel and/or audit process

Research institute funding

The definition of a medical research institute needs to be clear. Cancer Council NSW is one of many not for profit organisations operating as a medical research institute, but without recognition as such by the NHMRC, and therefore ends up being ineligible for Research Institute Infrastructure Support Scheme (IRIIS) funding. Success in receiving external competitive grant funding actually costs organisations like the Cancer Council money, and thus limits opportunities to participate in research.

We can point to major benefits we have achieved for Australia from our research – but our reward is to be denied participation in IRIIS, and to be left subsidising government funded research programs.

Similarly, research organisations such as ours, are not eligible for ARC funding as we are not recognised as part of the higher education system. This is in spite of the fact that our organisation has close associations with universities and acts as a training institute for higher degrees.

Cancer Council NSW meets every criterion stated on the NHMRC Accreditation Policy 2004, and has applied for accreditation several times. This is despite having creditable competitive grant performance. Cancer Councils Victoria and Queensland have received this accreditation.

If the intention of the criteria is to restrict market entry into research by the private sector, then this could be devised in a different way that does not disadvantage organisations like Cancer Council NSW that significantly invest in research.

We ask the Review Committee to recommend:

- A clarification of the definitions and eligibility criteria for medical research institutes
- That organisations like Cancer Council NSWbe eligible for research institute funding.

Research directed to groups at greatest need

Cancer Council believes there is a need for the Review Committee to ensure more research is directed to those populations with the greatest burden of disease and/or where there is a clear disparity in outcomes, in particular Aboriginal people. It is also vital that mechanisms are established that research be conducted in partnership with those best able to contribute - Aboriginal organisations.

Australia's ethnic diversity and changing racial composition should also be considered as a research priority area. With regards to cancer control, the changing racial composition in Australia has introduced subpopulations with unique cancer profiles and risk e.g. people from African nations may have had more exposure to the carcinogen aflatoxin; people migrating from Asian countries where hepatitis B virus is endemic are at significantly higher risk of liver cancer; and various ethnic groups have a higher risk for stomach cancer. Priority should be given to researching and addressing their unique needs, as well as promoting research among their communities.

Cancer Council also believes that there are research issues where clearly Australia must be at the forefront such as melanoma and Australian encephalitis.

We ask the Review Committee to recommend:

- Priority be given to increase research funding for Aboriginal health issues and for this research to be conducted in partnership with Aboriginal organisations.
- Priority be given to increase research funding for those subpopulations who have more recently migrated to Australia, and may have unique cancer risk profiles.

How can we optimise translation of health and medical research into better health and wellbeing? (Terms of Reference 4, 8, 9, 10 and 11)

Personalised medicine

Cancer Council recommends that the Review Committee consider the pressing challenge and significant opportunity of personalised medicine and the need to re-engineer research to pursue this area. Personalised medicine is the goal of delivering the right medicine to the right person and at the right time. Personalised medicine relies on genomic or genetic information about the individual to understand how their genetic make-up is different from individual to individual. Advances in the understanding of the molecular biology of cancer has spawned the development of new drugs targeted to exploit biochemical pathways which are drivers of tumour growth and biology. In addition, a deeper understanding of the mechanism of action of traditional chemotherapeutic agents is refining therapeutic strategies.

This area of personalised medicine could be an example of how research funders better embrace new technology. NHMRC should consider a technology horizon scan and ensure that Australia is ahead of the pack in research technology.

We ask the Review Committee to recommend:

- That NHMRC explore the best ways to embrace supporting research technology that positions Australia as a leader in personalised medicine.