Submission to McKeon Strategic Review of Health and Medical Research in Australia from the Australian Breast Cancer Tissue Bank

Background: The Australian Breast Cancer Tissue Bank (ABCTB) was established in 2006 as a result of successful funding obtained via the NHMRC Enabling Grant scheme in addition to funds obtained from the Cancer Institute of NSW and the National Breast Cancer Foundation. All three funding streams, in addition to a limited cost recovery mechanism are essential for the survival of the resource, which makes material and data available in an open and transparent manner to researchers nationwide.

The ABCTB wishes to address the following questions:

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

It is the opinion of the ABCTB that essential research infrastructure such as biobanks (including data banks) need a sustainable and long-term funding stream. The true worth of biobanks is not realised until several years into their operation, when a sufficiently large cohort of material/data have built up and clinical outcomes of patients are known, several years post diagnosis. It is also true that the value of such resources will continue to increase, as research results on the donor material are returned to the biobanks, and linked back to clinical information to enhance the dataset. Today's research studies routinely generate vast amounts of data and it is important that biobanks are positioned to be able to store and compute this information. Biobanks are therefore ongoing and long-term components of the health and medical research system, and funding these within the traditional peer-review system is inefficient and ultimately non-sustainable, as the NHMRC have determined in the recent position paper from NHREC.

Establishment of a national network of high quality biobanks operating at international best practice standards, and developing funding models to sustain such networks, would enhance the research activities of all Australian researchers requiring tissue and data for their studies. As researchers are increasingly, and justifiably, being asked to focus on the translational potential of their research, in order to more directly benefit the health of the Australian community, the demand for biospecimens and data for such research has increased dramatically in recent years, and will continue to increase in the future.

Moreover, while in the current genomic, proteomic, and metabolomic environment, access to such resources is essential for the progress of research studies, funding the costs of provision of material remains a problematic issue.

While current biobanks have been supported by a combination of federal, state-based, and not-for-profit sources, federal leadership in affirming the importance of biobanks has been instrumental to date in bringing non-federal funders together. Going forward, a national strategy, and federal leadership, must be established and maintained, if agreements between federal, state and not-for-profit organisations to fund biobanks are to be effective. Private sector involvement especially in regard to private pathology companies could also be encouraged to participate more widely in a not-for-profit manner.

- *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)

Associations between basic and clinical/translational science and health outcomes are becoming much better understood and biobanks play a critical role in providing the large number of specimens required to give statistical significance for such studies.

Material from biobanks is ideally placed to expedite research translation, by providing biospecimens and outcome data against which laboratory-discovered findings can be tested. Biobanks that accrue a complete profile on samples held, from diagnosis, through treatment and finally long-term follow up serve to expedite research projects that have the ultimate aim of being able to identify markers or other features within individual patients that track with health, disease prognosis, treatment response, or survival.

In addition, the implications of the disease sub-types can be tested: as the number of donors increases, the numbers of the various disease sub-types will increase and research focused on understanding clinical or biological features of such sub-types will be better able to be supported. This is particularly true of rare disease sub-types, which can be under-represented in research projects due to the difficulty in accruing enough cases to reach statistical significance.

The availability of biological samples and associated information of high quality has been the foundation of many of the most important advances in medicine in our time. Genomic medicine research in large international consortia is now contributing to current and future advances in disease risk prevention and treatment. Biobanks are also aligning with clinical trials groups - homogenous series of tissue samples treated in a uniform way are a valuable resource for studying response to current and more innovative treatments.

Biobanks also have the ability to expedite research studies by having a “research ready” cohort of material and data available, thus removing the need for a prolonged recruitment period of appropriate donors. However, the establishment and maintenance of such resources at a sufficiently high standard to be of value comes necessarily at a significant financial cost and this cost must be incorporated into the research landscape. Without such a mechanism existing biobanks will be unable to survive.

Going forward, the ABCTB believes that investment in eHealth initiatives and the ability and permission to provide linkage of clinical and outcome data with clinical samples also needs to be a major strategic direction.

In conclusion the ABCTB considers that long term strategic investment in bioresources and data strategies are essential components of a health and medical research system that is able to translate the findings of research for real benefit to the Australian community, and that federal leadership in promulgating a national strategy for biobanking is crucial to the continued existence of biobanks in Australia.