



# National Biobanking Strategy

## ***1. Rationale for a national biobanking strategy***

The NHMRC has recognised the importance and value of biobanks for research and validation of results in the biomedical sciences and the translation of research into medical diagnoses and treatment.

Biobanks are essential research tools for medical research. For example, large cancer biobanks underpin international collaborative studies seeking to identify genetic risk loci and somatic mutations in cancer and proteomic biomarkers, such as various Genome Wide Association Studies (GWAS), the International Cancer Genome Consortium (ICGC8), The Cancer Genome Atlas (TCGA9), the Early Detection Research Network (EDRN) and the Disease Biomarkers Initiative of the Human Proteome Organisation (HUPO).

Many of the same approaches are being undertaken in brain and other specific areas of human research.

Australia has a proven track record in establishing large tissue and DNA resources for specific projects that have enabled research that have led to major findings in areas such as cancer genetics, tumour biology, epidemiology, patterns of care, and psychosocial impact of cancer.

However, Australian biobanks currently operate largely autonomously, with each biobank having independent processes to manage the infrastructure and operations required both to collect/store/annotate biospecimens/data and to provide these materials to researchers who request them. This has led to an unfortunate tendency to duplication of infrastructure and effort.

In addition, infrastructure and expertise in biospecimen collection and processing is not uniform across diseases, and researchers who seek biospecimens appropriate to some diseases with major impact on the health of Australians, or who seek samples collected according to non-standard protocols, are currently underserved by existing biobanks.

Moreover, to date there has not been sufficient linkage between clinical trials, which collect excellent outcome data, but often little or nothing in the way of biospecimens, and laboratory based research which is often conducted on biospecimens with inadequate clinical outcome data. Similarly genetic epidemiology studies focused on risk may collect germline DNA samples but obtain little clinical follow up data. In addition, few tissue banks have historically collected tumour material, blood samples and extensive clinical follow up data.

There are clearly opportunities for improvement, with benefits for pharmacogenetic and pharmacogenomic studies.

The discussion that follows draws on the outcomes of Workshops NHMRC conducted in 2011 and 2012, and subsequent consultations with biobanks (including those funded by NHMRC through Enabling Grants), researchers and not-for-profit funders.

## **2. Strategic Objectives**

The purpose of a national biobanking strategy would be to establish and sustain organisational structures, networks, support facilities and processes that are of benefit to patients, the national interest and researchers. A national biobanking strategy could consist of five strategic objectives.

1. To facilitate and enable the development of a national approach to biobanking that makes facilities and infrastructure available to as many researchers and research organisations as possible.
2. To maximise collaboration between researchers, research organisations and key stakeholders on matters such as process and system formulation, equipment purchase and maintenance, human resource planning and international links.
3. To strengthen national and local training provision and capability development in biobanking and related facilities and equipment.
4. To advise governments and other funders as appropriate on the capital and operational investments necessary to ensure infrastructure is in place to serve current and future national biobanking requirements.
5. To operate a well governed, accountable and efficient national biobanking system that is responsive to the requirements of users and stakeholders.

## **3. Advantages of a national biobanking strategy**

There are six key advantages to a national biobanking strategy. Such a strategy:

- a. is a logical vehicle to promote closer interactions of biobanks with clinicians, surgeons and other health professionals, and to facilitate access to clinical specimens and pathology archives as a crucial component of healthcare delivery on a national scale;
- b. can harness synergies between existing and new biobanks, by establishing common approaches to governance, infrastructure and operational aspects of biobanking, particularly in IT;
- c. can begin to address the currently unmet need of many clinical trials groups to systematically accrue high quality biospecimens from patients enrolled and uniformly treated on multi-centre national and international clinical trials;
- d. could rapidly respond to researchers' needs by prospectively collecting particular tumour types or specific data points for particular research projects;
- e. would provide a coherent structure within which continuing support for biobanking can be negotiated with local, state and other sources, and provide recognition/support for training of bio-resource staff and others, and accreditation/certification of resources conforming to a defined set of standards; and
- f. can assist the NHMRC, through AHEC, with the development of ethical guidelines and policies to ensure the highest ethical standards and procedures.

A national biobanking strategy could also:

- g. help harmonise the quality and costs of tissue banking services across Australia;
- h. allow for, and build on, best use of existing facilities and expertise. National co-operation/reach should encourage the sharing of ideas, best practice and process improvements;
- i. promote adherence to Best Practice methodologies and financial targets that are measurable;
- j. promote educational opportunities and training;
- k. result in improved turnaround times for researcher applications through a process managing with networked arms; and

- I. be scalable and flexile so that as conditions change it will still be relevant (eg new activities can be easily added).

## ***Appendix 1: Principles underpinning a national biobanking strategy***

The transition to an integrated national approach to biobanking is a complex and delicate task. The following guiding principles could underpin the organisational structures and approach to biobanking in Australia:

- a. **National focus and vision** – a national strategy and model should enable and support a national focus and vision for biobanking of tissue, cell lines, DNA and associated health information.
- b. **Participation by a range of health and research organisations** – a national strategy should allow for participation by all compliant researchers and health professionals whether employed in public, private or not for profit organisations.
- c. **Scalability** – a single national biobanking strategy should facilitate growth in the number and type, or in the scale, of biobanks.
- d. **Streamlined national approach to ethics and approvals** – a national strategy should allow for future “accreditation” as deemed appropriate for members or participants.
- e. **Financial sustainability** – a national strategy should draw together a range of funding sources which may include national and international grants, direct cost of research (DRC) payments, philanthropic and disease specific charity support, membership fees and a range of user fees for cost recovery.
- f. **Operational efficiency** – a national strategy should seek to limit duplication of infrastructure and funded positions and to maximise “leverage” capabilities such as pathology departments and existing systems where they work effectively.
- g. **Maximum benefits to patients and the health sector** – a national strategy should have, at its core, the objective of delivering future benefits to patients and their families as well as researchers and research organisations.
- h. **National approach to IT systems and informatics** – a national strategy should seek to provide for maximum linkages and searchability of available banks by all compliant and approved scientists through the use of high quality IT systems and search tools.
- i. **Minimal bureaucracy** – a national strategy should minimise paperwork and bureaucracy and design issues such as privacy and permission into health sector workflows.
- j. **Involvement of consumers (patients, research participants) and advocacy groups** – a national strategy should allow for the active involvement of consumers, patients and advocacy groups.
- k. **Transparent and independent governance** – a national strategy should seek to be transparent and put in place independent checks and balances to ensure that actual and perceived conflicts of interests are managed appropriately.

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