



Australian Government

NHMRC National Institute for Dementia Research

THE AUSTRALIAN BRAIN BANK PROPOSAL AND BUSINESS CASE

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Accelerating research. Enhancing collaboration. Creating change.



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PROPOSAL

To establish the Australian Brain Bank as a much-needed national infrastructure resource to enable and facilitate research that addresses neurological diseases, in particular dementia and other neurodegenerative diseases associated with ageing.

SIZE AND SCALE

The Australian Brain Bank transforms currently operating brain banking sites into a single, nationally-coordinated effort. Brain banking hubs and nodes will efficiently collect tissue after death across Australia. The hubs will develop and maintain all data and collection standards, manage the national donor program, maintain a searchable inventory and manage all financial, communications, education and training, reporting and program monitoring functions. Hubs will receive brains from the nodes and be responsible for tissue processing, neuropathological examination and storage as well as the selection and release of tissue to researchers. Nodes will recruit donors as well as collect and perform initial processing of the brain tissue.

Value contributed other funding sources and in-kind: \$1.45 million annually (46% of total operating costs)

Funding required (two hubs and four nodes): \$1.7 million annually

Total operating cost post-implementation (two hubs and four nodes): \$3.15 million annually

Additional nodes: \$0.155 million annually per node (90% of total node operating costs)

BENEFITS

Improved brain health and ageing outcomes: Some health and ageing research can only be done by examining brain tissue post-mortem. The human brain is a unique and complex organ which cannot be fully modelled using other organisms. For example, there are types of nerve cells that are vulnerable in dementia, which are only found in humans. In addition, accurate disease diagnosis, which increases knowledge of age-related neurological conditions, can only be given by examination of brain tissue after death.

Increased research capacity and capability: We are entering an exciting time in neuroscience research; the development of big datasets through “omics” research, along with increased ability to comprehend them through artificial intelligence. These new developments are opening up exciting new ways of understanding the functional workings of human brain and how biology, genetics, the environment and behaviours contribute to brain health. Advances in molecular, biochemical and histological techniques are enabling human brain tissue to be part of these big datasets, with the promise of understanding changes at the level of single cells - from epigenetics to proteomics - and from cells to function. These advances intersect with new hope in ageing research; hope for prevention and hope for a cure for age-associated brain diseases.

Increased community involvement in research: Brain donation is highly personal and involves deep generosity, requiring high quality donor practices to ensure ongoing support from the community, donors, donor families and key stakeholders. The Australian Brain Bank will ensure regular and timely engagement with donors and their families from pledge to donation, including the sharing of research progress for as long as they wish to be informed.

IMPLEMENTATION PRINCIPLES

1. a strong governance framework, such that multiple organisations operating across diverse sites have shared responsibility and ownership of both process and outcomes
2. a sustainable ongoing operating plan that maximises revenue streams and in-kind support across existing and new government, university, industry and philanthropic sources
3. harmonised standards across all sites
4. a robust data management plan and research-user friendly searchable database platform
5. a training program to ensure ongoing expertise in brain banking, tissue handling and neuropathological characterisation of tissue
6. a communications strategy and ongoing stakeholder engagement program which meets the needs and expectations of researchers, government, industry and philanthropy and which has a particular focus on donors and their families.

PATH TO ESTABLISHMENT

CONSORTIUM APPROACH

- Existing brain banks commit current stakeholder/institutional support and contributions by way of pledge
- Government makes an initial investment of \$200,000 towards consortium establishment on the basis of pledges received
- Consortium establishes an independent steering committee to oversee development of Australian Brain Bank
- Government, philanthropic, institutional and industry investors pledge contributions to cover full costs: government leads by way of national infrastructure call to formalise arrangements and set in place funding agreements including setting of milestones and KPIs. Funding is held in reserve for future entrants/nodes.
- Australian Brain Bank consortium is formed as an unincorporated joint venture with a management committee and Director
- Steering committee provides oversight and advice to management committee
- Hubs and nodes are established
- Systems are in place
- Australian Brain Bank is launched
- Australian Brain Bank subsidises and on-boards new nodes by way of formal applications

INSTITUTION-LED APPROACH

- Government accepts business case and allocates funding, including holding funding in reserve for new entrants once the Australian Brain Bank is established
- Funding call is made for a single national Australian Brain Bank
- Applicants develop and submit consortium bid/s
- The successful administering organisation (presumably one of the hubs) appoints a Director and establishes management committee and administration
- Hubs and nodes are on-boarded by way of multi-institutional agreement. Management committee is formed with representation from all participating institutions.
- A condition of grant funding may include establishment of an independent advisory committee providing stakeholder and expert advice and guidance.
- Systems are in place
- Australian Brain Bank is launched
- Australian Brain Bank subsidises and on-boards new nodes by way of formal applications

BUSINESS CASE

EXECUTIVE SUMMARY

When a member of the community leaves their brain to medical research, they leave one of the most precious gifts to future generations. The human brain is at the pinnacle of evolution, responsible not only for maintaining the basic bodily functions of life, but also for all the higher cognitive functions that make us human. Only by understanding the human brain will we be able to solve the problems that arise when the human brain is overcome by disease, including those that cause neurodegenerative disorders such as dementia. We are entering an exciting time in neuroscience research; the development of big datasets through “omics” research, along with increased ability to comprehend them through artificial intelligence, is facilitating the understanding of the functional workings of human brain from the molecular level up. Advances in molecular, biochemical and histological techniques are enabling human brain tissue to be part of these big datasets, with the promise of understanding changes at the level of single cells - from epigenetics to proteomics - and from cells to function. These advances intersect with new hope in ageing research; hope for prevention and hope for a cure for age-associated brain diseases. In order to capitalize on these advances, we need to ensure that we maximize the precious gift of those that leave their brain to medical research.

Human brains donated to research are processed, characterised and stored at brain banks. Brain banks act as a repository to provide researchers with brain tissue and enable new discoveries. Australia is currently under-resourced for brain banking, putting Australian researchers at risk of being left behind in the brain sciences, Australian brain donors of being under-appreciated and the Australian population of being under-represented in the development of treatments to prevent or cure the biggest challenge in medical research for the 21st century — dementia and other neurodegenerative diseases. Furthermore, without a strategy for ongoing training, Australia is at risk of losing valuable neuropathology expertise.

We propose to rectify this shortfall by capitalizing on current brain banking expertise to bring together a single national brain bank for Australia, incorporating new technologies, harmonizing protocols nationally and internationally, enabling data sharing and linking crucial health data from valuable long-term studies and health records. The Australian Brain Bank will be a single entity, working under a hubs and nodes framework, combining multiple research organizations through a multi-institutional agreement and maximizing co-contributions from participating organizations. At the core of the Australian Brain Bank will be a single web interface, searchable by researchers to optimize their research, and engaging donors and community members.

Establishment of this vital infrastructure will require consolidation of current brain banking operations, the development of a new governance structure, including an over-arching Steering Committee with researcher and community input, and the achievement over time of financial sustainability. It is internationally well-documented that brain banks cannot succeed if they rely solely on cost recovery. Therefore, the Australian Brain Bank will operate under a mixed funding model, financed by a combination of University/Institute in-kind support, cost recovery and ongoing infrastructure support. The Australian Brain Bank will also engage with charitable organizations to support specialist brain collections, serving the needs of community and advocacy groups.

This business case puts forward the rationale, framework, funding model and proposed way forward to establish the Australian Brain Bank as a national research infrastructure resource for researchers, charitable organizations and members of the community. The four-year timeline will enable consolidation of current resources, establishment of governance systems, development and implementation of the framework, engagement of the research and donor community, and achievement of a robust and sustainable approach to operations, linked as appropriate to Australia’s broader biobanking agenda. The proposed public investment in establishing the Australian Brain Bank will deliver a new resource for the community and the next generation of researchers with a co-investment approach delivering ongoing sustainability in funding, operations and expertise.

CASE FOR CHANGE

Dementia leads to substantial morbidity and mortality in Australia

Dementia is the second leading cause of death for Australians and has been recognized as a public health priority by the World Health Organization⁽¹⁾. There are few people in Australia who are not affected by dementia and there is increasing recognition and public interest in dementia, not only in the older population, but also in the younger generation, for example driven by high contact sports. Dementia also has close links with other neurodegenerative diseases, such as motor neuron disease and Parkinson's disease. In the absence of a significant breakthrough, it is estimated that 6.4 million Australians will be diagnosed with dementia in the next 40 years, which will have a significant impact on Australia's healthcare system and aged care sector⁽²⁾. The cost of dementia in Australia is predicted to reach \$36.8 billion in 2056⁽²⁾. The World Dementia Council has set an ambitious goal of identifying a cure or disease modifying therapy for dementia by 2025⁽³⁾, which has the potential to reduce the cost of dementia in Australia. Developing treatments for dementia will rely ultimately on a better understanding of the changes that occur in the brain in dementia.

Well characterized human brain tissue is core to a research strategy to treat age-associated neurodegenerative diseases like dementia

The human brain is a unique and complex organ which cannot be fully modelled by other organisms. For example, there are types of nerve cells that are vulnerable in dementia, which are only found in humans. Therefore, researchers rely on access to well characterized human brain tissue for their work. To date, the major findings relating to our understanding of neurodegenerative diseases have come from human brain tissue collected after death^(e.g. 4,5) and Australian researchers have been at the forefront of this research. Brain banks are essential to supply researchers with case (disease) and matched control tissue for their work, which may eventually lead to cures for the different types of neurodegenerative diseases. Because of the need for case and control tissue, most brain banks hold diverse collections that contribute to various research topics on age-associated brain changes. Over 600 research publications have resulted from brain tissue supplied by Australian brain banks between 2004 and 2014⁽⁶⁾. In addition, accurate disease diagnosis, which increases knowledge of these age-related conditions, can only be given by examination of brain tissue after death and is performed at brain banks by neuropathologists.

Brain banking is necessary in Australia

There are a number of brain banks operating internationally which can be accessed by Australian researchers including the UK Brain Bank Network and the Netherlands Brain Bank⁽⁷⁾. However, brain banks are necessary in Australia because they reflect the characteristics and disease prevalence of our unique population, which needs to be represented in research. Brain banking in Australia accelerates our capacity to translate research, facilitates Australian participation in research, both internationally, and in collaboration with the pharmaceutical industry. It also attracts and retains high-quality researchers in Australia and ensures ongoing specialist neuropathology capability.

In addition to serving the needs of researchers, brain banking plays a critical role for the involvement of people living with dementia and other neurodegenerative conditions, their families and carers. It has the ability to heighten engagement by allowing these members of the community to contribute to future research on neurodegenerative diseases or by maximizing the knowledge gained by their contribution to cohort or clinical intervention studies.

Although fragmented, the current brain banks in Australia offer an opportunity for an integrated national approach

There are a number of brain banks currently operating in Australia. Some of the brain banks rely heavily on their State's Department of Health for collection and characterisation of tissue, however, others are independent of Departments of Health in their operations and receive substantial cash or in-kind support from their host organisations such as Universities or Medical Research Institutes. Although most of these brain banks were partially unified from 2004-2014 to form the Australian Brain Banking Network (ABBN), currently these brain banks

operate largely independently of each other and some now have no funding, resulting in their effective closure⁽⁷⁾. The lack of secure sources of funding has resulted in a lack of central operating or governance structure, thus leading to fragmentation, a lack of harmonization and restricted ability to provide researchers with reliable access to clinically, neuropathologically-documented and well-characterised brain tissue resources. There is also an inability to provide training for a future generation of researchers. Despite this, the remaining brain banks are run by a dedicated, passionate and experienced staff and therefore provide an opportunity for Australia to develop a new generation of researchers and neuropathologists, underpinned by the discipline of pathology with harmonized protocols, standardisation, efficiencies of scale, and provide a platform to share knowledge and resources to help lead the global effort to cure brain diseases associated with ageing.

The time is ripe to develop new integrated brain banking capacity in Australia

There have been a number of developments in research on ageing and neurodegenerative diseases which mean that a national approach to brain banking has become a priority. We have the first glimmer of hope that prevention and treatment strategies may be possible in dementia^(8,9). This means that for the first time we can see a way forward for the management of dementia. However, despite these promising findings there is a great deal more that needs to be understood before treatment strategies can be realized. Human brain banks will be essential in developing this understanding. Researchers need human brain tissue, particularly from individuals who have been part of clinical studies, including clinical trials, as these individuals have been well characterized during their lifespan through assessment of cognitive, biomarker, genetic, imaging and lifestyle factors. A harmonized Australian Brain Bank would allow the research community to capitalize on these invaluable studies and combine these data, collected before death, with the use of new technologies in the analysis of post-mortem tissue, including “omics” based research. These integrated big datasets will enable a personalized approach to the development of treatments for brain diseases and allow Australia to play a leading role in an exciting and promising chapter in the goal to reduce the burden of dementia and neurodegenerative disease globally.

The potential risks of not responding to the current need for an integrated brain bank in Australia

There are a number of risks to not responding to the current need for a securely-funded and integrated national brain bank⁽⁷⁾. In the current state, brain banks run the risk of failure to meet their long-term obligations to donors. As brain donation is highly personal and involves deep generosity, this may result in loss of credibility with the community, donors, donor families and other funders. The lack of funding and failure to meet these commitments has already resulted in dissatisfaction within the community⁽⁷⁾ and could jeopardize community participation in research in the future. The current state of brain banking also runs the risk of failing to meet the needs of researchers, with a lack of suitable tissue or unequitable access to tissue, lack of harmonization and reduction of research quality and failure to maximize outcomes from costly studies such as cohort studies and clinical trials. There is also the potential that the current state of brain banking would mean that the Australian population fails to be represented in research forums and as part of the global effort to find a cure for neurodegenerative brain diseases.

BUSINESS OBJECTIVE

An independent review was performed in 2019 by the Nous Group⁽⁷⁾ with the key recommendation that a national brain bank, acting as a single operational entity, would provide the most effective approach to deliver the core needs of brain banking in Australia. Their advice is the cornerstone to this Business Case. A national brain bank will provide for the current and future needs of researchers in neurodegenerative diseases and will be of wide benefit to the Australian community through enabling involvement in age-related research and positioning Australia to play a leading role in the national and global directive to reduce the burden of these brain diseases.

The brain bank should be a single operational entity using a hubs and nodes approach

Effective brain banking requires a number of activities which need to be effectively linked.

- Initially brain donors need to be recruited and consent to donate their brains after death. The prior knowledge of the donor's health and medical status is essential for high quality brain banking as donors with the same clinical condition can have markedly different neuropathology and, conversely, donors with the same neuropathology can have markedly different clinical conditions. Brain donors who have participated in clinical research, longitudinal cohort studies or clinical trials are ideal participants as they have already provided clinical, cognitive, biomarker, genetic, imaging and other data, as well as having demonstrated a commitment to neurodegenerative research.
- At the time of death, donor brains need to be collected as soon as possible to maintain the integrity of the tissue and subject to initial macroscopic characterisation and preparation.
- Collected tissue needs to be processed and undergo detailed neuropathological characterization and comparison with pre-mortem information.
- The tissue then needs to be correctly stored with details recorded in a central database.
- Researchers can then make requests for the tissue as part of a group of cases and controls needed for their particular ethics committee approved research study.

A single brain banking entity for Australia will have a number of advantages:

- single point of contact for researchers enabling optimal access to the tissue required for their needs
- harmonized tissue collection and processing protocols to optimize research data
- more consistent and secure experience for donors
- greater efficiency through enabling a critical mass of expertise with less likelihood of redundancy
- enhanced capacity for international collaboration in brain banking.

The hubs and nodes approach will ensure efficient collection of tissue after death from across the different states of Australia, but undertaken within a single operational entity. The hubs and nodes will be managed by a single central organisation, the Australian Brain Bank. The nodes will be involved in the recruitment of donors as well as the collection and initial processing of the brain tissue. In addition to the activities described for the nodes, the hubs will receive brains from the nodes and will complete tissue processing, neuropathological examination and store the tissue. The hubs will also be responsible for the selection and release of tissue to researchers.

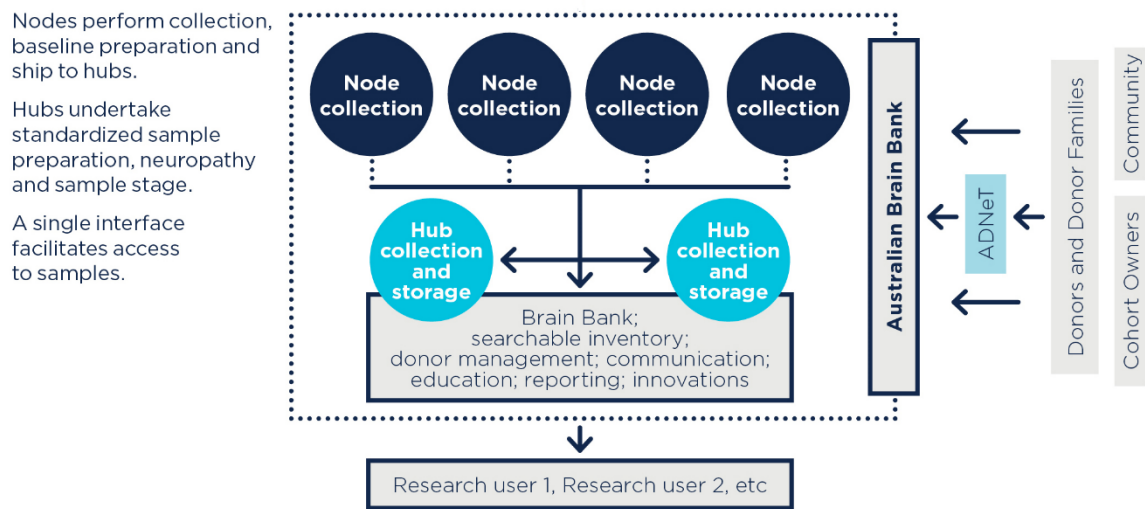


Figure 1. Diagram showing the proposed structure and operation of the Australian Brain Bank

A hubs and nodes approach provides substantial cost benefits over other models of operation as it allows the proposed Australian Brain Bank to make maximum use of in-kind support such as donor programs funded through research grants or charitable bodies, access tissue through State Health Departments and access other sources of infrastructure including from host and Universities or Medical Research Institutes, whilst reducing redundancy through centralised processing, characterization and distribution of tissue.

The single entity brain bank will provide for the current and future needs of researchers

In order to ensure that the Australian Brain Bank provides for the current and future needs of researchers, it will provide a number of functions in addition to the collection and storage of tissue. It will play a key role in promoting and enabling research using human tissue by providing ongoing training, education and resources to researchers and clinicians. It will engage with researchers to determine current and future needs and to stay in line with emerging technologies. It will also play a key role in public engagement which helps to increase accountability and transparency and promote public support.

The investment in the Australian Brain Bank will result in a number of downstream benefits including increased research capacity and capability, increased community involvement in research and potential impacts on health.

There is already clear evidence of need; between 2015 and 2019, 91 researchers supported by NHMRC-funded research grants accessed tissue from the existing brain banks, 228 projects funded by other funding sources accessed tissue, and there were 46 international tissue requests.

The Australian Brain Bank will also have the capacity to integrate into national or regional biobanks. Although brain banks are distinct from biobanks (e.g. samples are collected post-mortem and require significant specialized characterization), data linkage to national biobanks and data repositories would add substantial value to the precious donations of brain tissue, including allowing investigation of body-brain relationships.

A single entity brain bank will require a secure and sustainable source of funding

Funding for brain banking is usually provided by a combination of cost recovery, philanthropic contributions, cash and in-kind funding (e.g. from Universities, Medical Research Institutes or other partner organizations) and direct core grant funding⁽⁷⁾. Successful brain banking requires an ongoing source of core funding because supply and demand can be inconsistent and is dependent on factors such as the availability of researcher grant funding and philanthropy⁽⁷⁾. Stability in funding is essential to mitigate reputation risk and ensures that the donor’s commitment

to brain donation, which can be long-term in nature, is honoured at the time of death. In this regard, fragmentation of funding is recognized as a key issue for brain banks internationally. A core business objective of the Australian Brain Bank will be to develop and acquire a range of sustainable sources of funding.

An initial investment is needed to enable the consolidation of brain banking in Australia, to ensure current expertise is not lost, to maintain the reputation of brain banking with the community and ensure Australia's role in the global effort to find cures for neurodegenerative diseases.

IMPLEMENTATION PRINCIPLES

Establish communication strategy with donors and their families

Brain banking plays a significant role in the community's involvement in research into neurodegenerative diseases and regular and timely engagement with donors and their families is fundamental to the success of the brain banking process. This engagement is important for ensuring that these essential community contributions are respected and valued. There is an exciting opportunity for the Australian Brain Bank to link in with many community-based research cohorts for donor recruitment, including through the recently formed Australian Dementia Network (ADNeT). ADNeT aims to link dementia researchers, clinicians and the community through a clinical quality register, a network of memory clinics and better links between clinical trials and potential participants. Donors from research and clinical cohorts and the general community will receive appropriate information, ongoing support and engagement through the Australian Brain Bank. The Australian Motor Neurone Disease (MND) Registry is one of a number of other relevant registries with similar functions and capacity, and an expressed willingness, to collaborate in donor recruitment for the Australian Brain Bank.

Develop a training plan to ensure ongoing expertise in brain banking, tissue handling and neuropathological characterization of tissue

Brain banking for the use of human tissue in research requires a specialized skill set which needs to adapt to changing research needs as new technologies are developed. In particular, neuropathology expertise is required for the high-quality characterisation of donated tissue and is critical to maximise the usefulness of donated tissue. There is a shortage of diagnostic neuropathology expertise both nationally and internationally due to limited career progression and training opportunities. Opportunities to manage this risk may be possible through working with states and territories to encourage uptake of this specialization in clinical training or through the American Association of Neuropathologists Scholars Program, which offers a NIH-funded career development workshop.

Develop a data management plan including a searchable database with interface for interaction with researchers

Brain banks collect data from numerous sources including donors, clinicians, longitudinal research studies, clinical trials, etc., as well as data obtained during the collection, processing and characterisation of donated brain tissue. This data collation process may span many years. Good sources of data contribute substantially to the quality of research outputs from the donated tissue and are therefore an essential feature of good research practice. Wherever possible, a minimum standard data set will be collected across all brain donor programs, nodes and hubs to allow correlation of research data with that from international brain banks as well as the potential to link the Australian Brain Bank resources into other national and state-based biobanks.

The Australian Brain Bank will provide a searchable database for researchers, with the resulting readily accessible information about existing inventory enabling:

- a transparent and unbiased platform for researchers to access tissue

- researchers to design experiments appropriately, submit more competitive funding applications and quickly assure ethics committees of the soundness and feasibility of studies
- cost effectiveness, as it reduces time spent by brain bank staff in fielding enquiries
- data sharing, including neuropathology slides and big datasets obtained from the tissue.

To encourage collaboration, the Australian Brain Bank database will also facilitate linkages to other specialist tissue collections, nationally and internationally, particularly those which are outside the scope of the Australian Brain Bank and therefore ideal brain banking collaborators.

Harmonise standards to current good practice to ensure the consistency and quality of banked tissue

Data obtained from human tissue is affected by the way that the tissue is processed and stored, therefore consistent protocols need to be adhered to across all participating sites within the Australian Brain Bank in order to reduce variability and maximise the value for researchers accessing tissue. Harmonisation of standards to match international practices allows researchers to access tissue from multiple banks while minimising confounding factors. Harmonisation of standards includes consistency in processing, clinical diagnoses and characterisation criteria, the type of data collected (such as case characterisation information and photographs) and how it is made searchable for future use. The Australian Brain Bank protocols will be prepared in consultation with researchers to assess researcher needs and will be made available for use by researchers with specialist collections outside the scope of the Australian Brain Bank. This process should remain sufficiently flexible to change in line with evolving good practice and the development of new technologies using human tissue.

Ongoing stakeholder engagement

A number of challenges have been identified in the biobanking discipline including variable public confidence and perceived limitations to biospecimen access⁽⁷⁾. To address these barriers, our national approach will include ongoing stakeholder engagement including consumer and researcher representation within the governance structure, as well as education to increase knowledge and understanding of brain banking and the value that it has to research.

SCOPE

Disorders and types of tissue

The Australian Brain Bank will collect brain and spinal cord tissue (where appropriate) for all neurological disorders as well as control brains, focusing on tissue to be used for research purposes and where there is a demonstrated research need. It will be the responsibility of the brain bank Management Committee to monitor supply and demand of brain tissue to ensure that funding is directed to collecting and storing tissue that is most beneficial to national research priorities. Tissue from control cases (defined as no diagnosis/evidence of neurological disorder prior to death) will also be collected from adults >18yrs of age. Control tissue is in short supply globally and pre-screening for suitability will be carried out where possible. There are limited resource options for control brain tissue. Victoria has the support of their state coronial system to access control cases. Other states may also be able to establish collections through their state coronial systems. Brain collections from past and current brain banks across Australia may be able to be consolidated in the establishment phase. These will remain the responsibility of the current custodians (including the associated costs) unless their inclusion in the Australian Brain Bank can be fully justified in line with the implementation principles outlined (including researcher need, availability of phenotypic data, agreement to adopt standardized collection and maintenance protocols). Currently operating brain banks will be prioritized for inclusion.

Tissue collections

Brain donor programs resulting from recruitment of individuals who are participants in longitudinal cohort studies, or other research or clinical studies, or clinical trials offer an opportunity to value add to the brain bank by providing tissue from individuals who have been well characterized during life and enabling clinicopathological comparisons. Donor programs will be on-boarded via an application process to ensure suitability of the donor tissue. It is recognized that, in some circumstances, tissue rights may need to be maintained by principal investigators and in these cases the brain bank may offer a fee-based service for collecting, characterizing and storing of the tissue. Such collections could remain separately managed and linked to the Australian Brain Bank through harmonization of protocols and listing in the database to encourage collaboration, data sharing and increased scope.

Hubs and Nodes

The Australian Brain Bank has the potential to involve all states and territories and could involve sites outside of capital cities. In the initial stage of the project, a number of organizations that currently undertake brain banking will be brought together to collaborate in the formation of the Australian Brain Bank. These organizations will be those with established brain banking expertise (Appendix 1), those with community-based donor cohorts willing to participate, and agencies and advocacy and charitable groups with an interest in brain banking. Hubs and nodes will be established based on the levels of commitment and contributions they can make (including operational arrangements, in-kind support and funding contributions) as well as their feasibility in meeting the needs of Australia's ageing and neurodegenerative research. It will be the responsibility of the individual hub or node to propose feasible arrangements for ongoing operations, and to address the challenges of differing geographical locations.

Hubs

It is recommended that the Australian Brain Bank have two hubs, reflecting the developed level of infrastructure and skills within the country. This approach will mitigate the risk of holding tissue at only one site, reduce transport costs, and provide better access to tissues across Australia. The hubs will be the main tissue processing, analysis and storage sites for the Australian Brain Bank. They will perform all the activities of the nodes but in addition, they will receive and process brains from the nodes as well as the brains they collect, including neuropathological characterization (macroscopic and microscopic examination and histology). They will store and maintain tissue and supply tissue upon request of the Australian Brain Bank administration to qualified approved researchers. They will be responsible for updating tissue records on the database and work with the Management Committee to manage tissue stocks. They will also be responsible for maintaining and monitoring their own infrastructure (including freezers), and ethical and quality compliance.

Nodes

In the initial establishment of the Australian Brain Bank it is recommended that sufficient funding be provided for the establishment of four nodes or collection sites in areas of demonstrated need⁽⁷⁾. There will therefore be six collection sites in all, as the two hubs will also be collection sites. The nodes will be key sites for retrieval of tissue and will be responsible for initial basic processing as well as packing and transporting the tissue to the hubs. The nodes may also play a role in recruiting donors and referring them to the central administration as well as developing relationships with local clinicians, disease associations and funeral directors. They may contribute to collecting donor information and will also be responsible for maintaining and monitoring their own infrastructure (including freezers), and ethical and quality compliance obligations relevant to their own operations. This will be important, because legislative arrangements differ across the Federation.

While not part of the planned initial stage, there is an opportunity over time to increase collaboration particularly through identifying organisations that would bring new innovations in brain banking such as data sharing, new technologies for examining human tissue, or contribute tissue through additional nodes on a needs or opportunity basis.

Stakeholders and partners

The establishment of the Australian Brain Bank will attract a number of other stakeholder groups who will be able to support and enhance the effectiveness of this initiative. These stakeholders range from individual members of the community to disease-associated charities, government entities and philanthropic organisations. The Australian Brain Bank will provide an opportunity for members of the community to both contribute to, and benefit from, research, and therefore brain donors and their families, people with dementia and/or other neurodegenerative conditions and their carers will be key stakeholders. Not-for-profit organisations and peak bodies who work with these disease groups have a direct interest in supporting brain banking to contribute to improvements in diagnosis and treatment of their respective disorder. Organisations such as Dementia Australia, MND Australia, Parkinson's Australia, Fight MND, MS Australia and MS Research Australia would be expected to support the Australian Brain Bank. Philanthropic organisations with a mission to improve the health and wellbeing of those living with, or at risk of, neurodegenerative disorders are also expected to engage with the establishment of the Australian Brain Bank.

Other key stakeholders include members of the research community including those who undertake research into neurodegeneration, those who lead cohort, longitudinal, clinical studies and clinical trials, both nationally and internationally, those who use human tissue in their research (current and future users), other brain banks, and medical professionals with an interest in neurodegenerative disease. State and federal government departments and agencies are also key stakeholders in the establishment and success of the Australian Brain Bank.

GOVERNANCE AND MANAGEMENT

Two options are put forward for conducting an open and transparent grant application or tender process in which the applicants (e.g. Chief Investigators) will need to detail the operational and administrative plans for the delivery of the Australian Brain Bank. It is expected that the applicants and their host organisations will have a history of delivering similar organisational structures and delivering similar research infrastructure and have a commitment to providing in-kind support for the Australian Brain Bank. A governance and management structure will be established to ensure the transparency, equity, effectiveness, compliance and accountability of the Australian Brain Bank. It is anticipated that the Australian Brain Bank will be either:

1. a consortium, the membership of which in the initial stages would reflect Australia's currently operational brain banks
2. an unincorporated joint venture, delivered by an appropriate lead organisation (e.g. an NHMRC-approved Administering Institution) which will be the Operations Core, with other participating sites operating under multi-institutional agreement.

The governance of the Australian Brain Bank is proposed to be comprised of:

1. an independent oversight body that will provide strategic advice, review and endorse the strategic and operational plans of the Management Committee, and consider risk as well as monitor performance against milestones and key performance indicators
2. a management committee, comprising the applicants and/or Chief Investigators who will be responsible and accountable for the delivery of the Australian Brain Bank.

Other advisory structures may be considered, for example the establishment of a stakeholder and end user advisory body to provide insights and advice towards oversight, management and operations.

Australian Brain Bank Virtual Operations Core

The Australian Brain Bank Virtual Operations Core will be comprised of hub staff and will deliver all core functions. The Virtual Operations Core will include the roles of Director, Operations Manager, Donor Coordinator (to support brain donor programs), Tissue Request Coordinator (to support the review and fulfilment of tissue requests) and a Database Coordinator (to support the website and database) – which will be full-time or part-time contingent on workload and volumes.

The Virtual Operations Core will be responsible for:

- the website and database, obtaining and maintaining donor records, communicating with donors, managing tissue requests, and monitoring tissue stocks
- the budget, cost recovery and seek additional funding sources
- engagement of and communication with key stakeholders
- secretariat support for the governing bodies
- reporting the outcomes of the Australian Brain Bank to relevant funders, researchers and the community, with and through hub and node leads.

Oversight

The Steering Committee will provide scientific and strategic advice to the management committee and review and endorse the strategic and operational plans of the management committee. The Steering Committee will have an independent chair and include representatives of stakeholder groups and members with relevant skills and expertise. Once established, it is anticipated that the Steering Committee will meet twice yearly to support the development the Australian Brain Bank. Members will have skills and expertise from across the range of relevant brain bank activities and interests. The oversight body should not exceed 12 members who should also capture appropriate gender, geographic and other diversity and is proposed to include the following members:

- a Chair who is independent of the management committee
- management committee Chair (this position may be filled on a rotating basis by consortium members/collaborating institutions)
- administering institution representative
- stakeholder representatives (3). This may include one person each from the collaborating institutions, not-for-profit disease focusing community or advocacy groups, and philanthropic organisations
- expert in human ethics
- Organ and Tissue Authority representative
- International Brain Bank representative
- community representative - a person living with dementia or other neurodegenerative disease, a carer or a donor family member
- research representatives (2) - an established brain tissue researcher and an early/mid career researcher or postgraduate student representative.

Management Committee

The Australian Brain Bank Management Committee will be Chaired by the Director and will include a representative from all hubs and nodes, once established. The Management Committee will set and implement strategic and operational plans of the Australian Brain Bank and includes those individuals who are responsible and accountable

for the delivery of the Australian Brain Bank. The Management Committee will develop standards and for both the use by the hubs and nodes to ensure sample acquisition and storage, neuropathology characterisation and tissue quality, ensure techniques are up to date, fill tissue requests endorsed by the Scientific Review Committee, and implement data sharing through a unified database.

The Management Committee, in consultation with the Steering Committee, will establish key sub-committees to ensure the timely and effective delivery of the objectives of the Australian Brain Bank, each led by a member of the committee but composed of other staff members associated with the (including hub leads, staff and researchers).

Scientific Review Committee

This committee will conduct an independent scientific review of applications for tissue to ensure that material from the Australian Brain Bank is distributed based on scientific merit. Objective criteria for evaluation of applications for tissue will be established. The committee should be composed of 6-10 researchers with expertise in neuroscience and/or human tissue research who can undertake the scientific review of applications, aided by independent referee reports as required. All decisions are to be made within the framework of a rigorous conflict of interest policy. The Chair should be a member of the Management Committee. The work of this committee will be assisted by the Tissue Request Coordinator.

Marketing and Communications Committee

This committee will support activities related to donor engagement, researcher education, promotion of the Australian Brain Bank. It will oversee website, database development and external communications. The Chair should be a member of the Management Committee. The work of this committee will be assisted by Tissue Application Coordinator and the Database Coordinator.

Research infrastructure

The physical research infrastructure to support activities of the Core, Hubs and Nodes will remain under the guardianship of the Australian Brain Bank, which will be responsible for ensuring maintenance, repair and replacement as needed. The host institutions will provide laboratory and office space as an in-kind contribution and will be encouraged to make additional in-kind contributions of equipment and other infrastructure as part of the hubs and nodes establishment process. Responsibility for maintenance and replacement of research infrastructure and equipment that is owned by other parties will be subject to negotiation at start-up.

ACCESS AND COST RECOVERY

Accessing tissue and reporting outcomes

The Australian Brain Bank will establish an independent Scientific Review Committee to ensure appropriate use of collected tissue. An independent scientific review of each application for brain tissue will assess the request based on scientific merit using a standardised set of criteria to be endorsed by the Steering Committee. Applicants will have access to an appeals process for tissue requests that are not approved. The Operations Core and Tissue Request Coordinator in particular, will work closely with the Scientific Review Committee to database all aspects of the review process.

The Australian Brain Bank Virtual Operations Core will establish a website with a single searchable inventory to provide researchers with clear and detailed information about the tissue available (including the minimum data and type of tissue available) as well as instructions for accessing the tissue through an online application process. This database will be integrated with the tissue review process and include mechanisms to capture annual reports on tissue usage from researchers. These reports will be available to the Scientific Review Committee to view at the

time of amended or new applications from the same researcher and will be available for reporting outcomes of the Australian Brain Bank. This will increase transparency, efficiency, research outcomes and user experience.

The Tissue Request Coordinator will manage applications for tissue, including communicating with researchers and providing a cost recovery estimate, organizing the review by the Scientific Review Committee, providing advice (if needed) and coordinating the distribution of tissue from the hubs, organizing Material Transfer Agreements, and cost recovery following tissue disbursement. The Tissue Request Coordinator will report and monitor appropriate recognition of the Australian Brain Bank on publications and presentations.

Cost recovery

In Australia, legislation in each State prohibits trade in human tissue but allows its lawful possession. As a not-for-profit research resource facility, the Australian Brain Bank will seek cost recovery to compensate for the costs associated with collection, preparation, characterisation, storage and provision of tissue, as outlined in this document, but will not apply a charge for the tissue itself.

Merit-based academic research

Researchers are able to fund their tissue requests through grant applications from national and philanthropic granting bodies including NHMRC, the Medical Research Future Fund (MRFF) and Dementia Australia Research Foundation (DARF). Based on current charges, the Australian Brain Bank will initially charge cost recovery to cover approximately one sixth of the costs associated with retrieval, processing, assessing and storing of brain tissue (Appendix 2). The Australian Brain Bank plans to build on this to cover one third of the costs by the fourth year of this proposal (Figure 2), which is in line with the UK Brain Bank Network⁽¹⁰⁾. However, as noted in the Nous Group report,^(7, pg44) charges will be subject to market demands and will be reviewed annually. These charges will price each tissue sample on average at \$24-\$48 (years 1-4), with an average of 160 samples per tissue request⁽⁷⁾ and an average cost recovery of \$3,840-\$7,680 (years 1-4) per request.

Commercial and other research

Based on international standards,⁽¹⁾ the Australian Brain Bank will seek to recover the full costs associated with retrieval, processing, assessing and storing of brain tissue, with a per sample cost of \$144 for commercial users of brain tissue.

RESOURCE PROJECTIONS

Based on the independent report by the Nous Group⁽⁷⁾ the Australian Brain Bank is predicted to have a total operating cost of \$2.8 million in Year 1 and \$2.8 - \$3.1 million in Years 2-4.

Resource projections build on the modelling of the Nous Group⁽⁷⁾, which used baseline data from the Australian Brain Bank Network for 2014. This business case allows a transition time and provides more accuracy by reference to actual current costs that were provided by currently operational Australian and international brain banks to ensure feasibility of the model. The model also assumes a 2.0% increase in operating costs per year.

	2014	2021	2022	2023	2024
New Donors	230	145	165	185	205
New Donations	180	110	150	165	185
Tissue releases	110	70	75	80	90

Table 1. The predicted numbers of donors and tissue requests over the 4 years of the business plan. Numbers are based on current numbers of registrations in active brain banks in 2021, building towards numbers achieved by the Australian Brain Bank Network in 2014

Staffing

According to the proposed plan, 9.4 FTE staff will be required in year 1 across the Virtual Operations Core and Hubs for the operational aspects of the brain bank. This will increase to 10.4 FTE in year 2 and 11.2 FTE in years 3 and 4 as operations increase and nodes come on board. Numbers of staff are based on modelling by the Nous report.⁽⁷⁾

The following staff will be needed at each of the locations:

Virtual Operations Core

Four key positions will be needed for operations core. A Manager (1 FTE) will have oversight of and overall responsibility for the day to day operations of the Australian Brain Bank. The Donor Coordinator (1 FTE) will be responsible for all aspects of recruiting, managing and engaging with brain donors and will also perform administration tasks as required by the Manager. The Tissue Request Coordinator (0.6 FTE in years 1 and 2, increasing to 0.1 FTE thereafter) will manage researcher interactions and tissue requests, working with the hubs. A Database Coordinator will be required at 1 FTE in the first year during establishment of the brain bank to establish the database and then be required at 0.2 FTE to ensure the database is kept up to date. A part-time Project Officer will also be required to visit inactive brain banks and to consolidate current brain tissue in the first year of the project.

Virtual Operations Core activities will be shared between the hubs.

Hubs

Each hub will need a Hub lead (1 FTE) who will manage the day to day operations of the brain bank, including coordination of brain retrieval, liaising with the donor coordinator and hospital staff, and managing approved tissue requests. A Research Officer (1 FTE) and Research Assistant (0.4FTE in years 1 and 2 and 0.6 FTE thereafter) will also be required to process fresh tissue, preparing tissue blocks and samples, assisting the neuropathologist, assisting with brain retrieval and receiving and processing interstate node cases. Neuropathology expertise will be provided in-kind from current experts but an additional two 0.2 FTE positions will be required for training and to expand expertise in this area.

The current Victorian and NSW brain banks support brain donor programs, collect, process and characterise brain tissue and supply tissue to meet researcher requests. It is anticipated that these sites will form the hubs of the new Australian Brain Bank.

Nodes

Each node will require a Research Officer at a minimum of 0.6 FTE to support collection, temporary storage, transport and liaison, as well as ensure skills and expertise are retained in each node. These will be required from the last quarter of year 1. Other salaries such as Principal Investigators for each site will be provided in-kind.

A number of states have had, and continue to have an interest in supporting brain banking (Appendix 1) and they would be well placed to bid for hosting a node of the Australian Brain Bank.

Financial model

The operational costs associated with brain retrieval and neuropathology per donation in year 1 is \$2,850 in the hubs (neuropathology \$950; body transfer for brain retrieval \$1,000; mortuary fee \$900) and \$3,550 (cost in hubs plus \$700 transport to hubs) in the nodes. Based on a model of 110, 115, 120, 125 (years 1-4) donations at the hubs and 0, 35, 45, 60 (years 1-4) donations at the nodes, the cost of brain retrieval will be \$313,500 in year 1 rising to \$604,020 in Year 4 (including 2% inflation).

The cost of research equipment and infrastructure including freezers, computers, cameras and mobile phones will mainly be in Year 1 of the project. In addition, hubs will need an additional 2 freezers per year. Maintenance costs are predicted to increase at 2% per annum over the project.

A detailed budget is provided in Appendix 3.

FUNDING MODEL

Development of a sustainability plan is core to the success of the Australian Brain Bank. Past national and international brain banks have demonstrated that brain banks cannot be financed by cost recovery alone and will require an ongoing source of funding to meet the needs of the general and research community⁽⁷⁾.

The Australian Brain Bank will operate under a mixed funding model and will source its funding from a number of avenues including in-kind contributions from host institutions, ongoing public funding, and with proposed support from industry and philanthropic organizations.

Based on predicted brain donations and tissue requests⁽⁷⁾, the brain bank will have total ongoing costs estimated at \$2.8 million in Year 1. This includes approximately 25% in-kind support from host institutions and a modest level of philanthropic donations. Ongoing costs, including in-kind contributions are estimated at between \$2.78 million - \$3.15 million per annum for Years 2–4, with requested funding of \$1.7 million annually. Together with cost recovery, almost 50% of Australian Brain Bank annual turnover will be non-government funding.

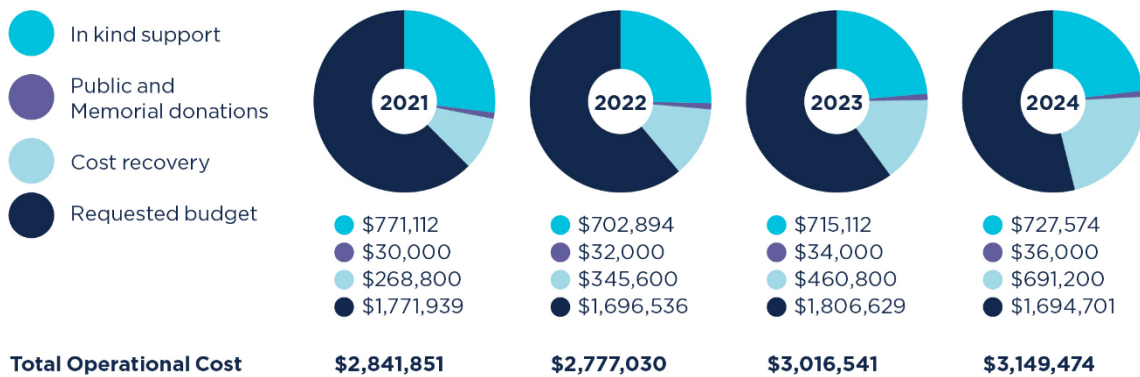


Figure 2. Estimated funding requirements for the initial four years of the Australian Brain Bank.

Given the recent closure of several brain banks in Australia and the financial strains on all currently operating sites, this proposal is a call to action on public investment in brain banking. Two possible approaches are put forward for this initial, vitally important investment in establishing the Australian Brain Bank.

CONSORTIUM APPROACH

- Existing brain banks commit current stakeholder/ institutional support and contributions by way of pledge
- Government makes an initial investment of \$200,000 towards consortium establishment on the basis of pledges received
- Consortium establishes an independent steering committee to oversee development of the Australian Brain Bank
- Government, philanthropic, institutional and industry investors pledge contributions to cover full costs: government leads by way of national infrastructure call to formalise arrangements and set in place funding agreements including setting of milestones and KPIs. Funding is held in reserve for future entrants/nodes.
- Australian Brain Bank consortium is formed as an unincorporated joint venture with a management committee and Director
- Steering committee provides oversight and advice to management committee
- Hubs and nodes are established, with hubs working together to set up the Virtual Operational Core
- Systems are in place
- Australian Brain Bank is launched
- Australian Brain Bank subsidises and on-boards new nodes by way of formal applications

INSTITUTION-LED APPROACH

- Government accepts business case and allocates funding, including funding held in reserve for new entrants once the Australian Brain Bank is established
- Funding call is made for a single national Australian Brain Bank
- Applicants develop and submit consortium bid/s
- The successful administering organisation (presumably one of the hubs) appoints a Director and establishes management committee
- Hubs and nodes are onboarded by way of multi-institutional agreement. Management committee is formed with representation from all participating institutions.
- Hubs work together to set up Virtual Operational Core
- A condition of grant funding may include establishment of an independent advisory committee providing stakeholder and expert advice and guidance.
- Systems are in place
- Australian Brain Bank is launched
- Australian Brain Bank subsidises and on-boards new nodes by way of formal applications

Public funding

The Nous Group independent consultancy found that international comparison banks and bank networks received substantial and long-term funding commitments from public sources. In Australia, sources of funding for research infrastructure are currently limited and there is no single source of funding that provides a way forward for brain banking. While support from universities and research institutes is integral to current brain banking operations, it is currently not sufficient to ensure a sustainable future. In the current climate, these institutions are needing to direct their research block grant funding towards maintaining research capacity at a time when research programs are facing unprecedented disruptions. They are increasingly unable to support new national infrastructure and will struggle to maintain subsidies to existing platforms.

Nous Group found that all biobanks, regardless of tissue type collected, face funding challenges and tend to source funding from a number of direct and in-kind sources to remain operational. Biobanks collecting brain tissues face these funding challenges with added complexity, as tissue collection occurs after death and therefore sits outside of state/territory standard healthcare collection protocols and funding structures. The complexity of sample collection and preparation, and the logistics of sample storage further differentiate brain banking from other biobanks. From a research perspective, brain tissue is a prerequisite for the study of neurological disorders and is currently the only means to establish an accurate diagnosis. The dominant funder of dementia research activity is

the NHMRC, which does not provide funding for research infrastructure such as brain banks. The MRFF is also supporting targeted research investments through the Dementia, Ageing and Aged Care Mission until 2028-29.

The National Collaborative Research Infrastructure Strategy (NCRIS) is the Commonwealth's primary direct investment in research infrastructure. Funding decisions under NCRIS reflect National Research Infrastructure Roadmaps and the criteria of the NCRIS program. NCRIS undergoes a biennial national research infrastructure investment planning cycle, as well as undertakes scoping study work with the sector on emerging research infrastructure needs, to inform successive iterations of the Roadmap. Current scoping study work includes exploring opportunities to network Australia's biobanks across agriculture, plant science, environmental science and biomedical science into a national rather than a disparate capability.

The MRFF 10-year investment plan includes funding for National Critical Infrastructure of \$605 million over nine years, beginning in 2019-20, and for Research Data Infrastructure of \$80 million over eight years, beginning in 2020-21. These funding schemes may present potential sources of funds for establishing national-scale dementia brain banking, and the necessary supporting data infrastructure to manage sample inventories and clinical information.

Nous Group modelling indicated, and an examination of actual financials from currently operating Australian brain banks has confirmed, that the proposed public investment will be matched almost dollar for dollar in a mixed funding model that has been shown to be successful across comparable brain banking operations internationally.

In-kind support

The structure of the Australian Brain Bank as a single entity delivering its services through linked hubs and nodes will maximize in-kind support from the collaborating organizations. As part of their commitment to the brain bank, participating institutions will provide core laboratory and office space, as well as maintenance, as in-kind contributions. Universities and Medical Research Institutes will also provide neuropathology expertise, IT infrastructure and marketing expertise. Chief Investigators' salary for each of the hubs and nodes, Management and Steering Committees, will also be provided as in-kind contributions, as well as administrative and operational support (e.g. for staff recruitment, procurement, cost recovery invoicing, etc.). The total in-kind support is estimated at \$0.77 million in Year 1 and \$0.70-0.73 million in Years 2-4.

Cost Recovery

Based on projected tissue requests for research use, cost recovery is expected to generate approximately \$0.27 million in Year 1, rising to \$0.69 million in Year 4 (Appendix 2).

Philanthropic support

Philanthropy may provide some opportunities for expanding funding for the Australian Brain Bank. Current support of \$0.03 million per annum comes from public and "in memoriam" donations. There is scope to expand philanthropic support through major donations from individuals, trusts and foundations. Furthermore, developing strong brain donor programs, with engagement and communication across the brain donor communities, has the potential to build support for human tissue research and the Australian Brain Bank. The Australian Brain Bank, through the Virtual Operations Core in association with the Marketing Committee, will engage with philanthropic organisations to increase this pool of funding.

Other organisations, such as the disease-based charities (e.g. Fight MND and MS Research Australia) may wish to provide support to enable specialist brain collections that are beyond the current scope of the Australian Brain Bank. These collections would advance research into their specific areas of focus and would build in the capacity and expertise of the Australian Brain Bank.

IMPLEMENTATION PLAN

Stage 1: Development (Year 1)

Appointment of key personnel and establishing the relevant financial, ethical and operational aspects of the Australian Brain Bank is expected to take 6-9 months. Working groups will be formed, under the direction of the Management Committee to put the following structures in place:

- consolidation of current brain banks: Consolidation of the current brain banks will be coordinated by the hubs. Site visits will need to be undertaken in order to assess current brain bank tissue for inclusion or disposal and consolidate information and databanks
- harmonized ethical framework (taking into consideration relevant State Legislation and Human Tissue Acts), standardized protocols, a framework for recruitment and management of donors and a reporting framework
- database and website, including working with the Marketing and Communications Committee to ensure the database and website are fit for purpose
- sustainability plan including cost recovery, in-kind contributions, other grant support and philanthropic support.

Stage 2: Establishment (Year 2)

The new protocols, website, database and cost recovery systems will be trialled in Year 2. Remaining equipment such as computers, fridges, freezers and histology processing equipment will be acquired and installed. The Australian Brain Bank will enact plans for donor recruitment, sustainability, stakeholder engagement, education, researcher and neuropathology training and promotion activities. All Committees will become fully operational including the Scientific Review Committee and the Marketing and Communications Committee. Training of all research staff will occur with a face to face workshop at one of the hubs to establish operating procedures.

Stage 3: Operation and review (Years 3 and 4)

By Year 3, the Australian Brain Bank will be fully operational at both hubs and nodes. Full review of operations will be conducted across year 4 to refine operational procedures and management. This review will include analysis of financial management, scope, sustainability and cost recovery to ensure that the brain bank is fully meeting the needs of the Australian and international research community.

MILESTONES

Milestones	Year 1				Year 2				Year 3				Year 4			
	1	2	3	4	1	2	3	4	1	2	3	4	1	2	3	4
Staffing Plan																
Recruitment of Brain Bank Manager	■															
Recruitment of Hub Coordinators	■															
Recruitment of Database Coordinator, Tissue Request Coordinator and Donor Coordinator		■														
Recruitment of Administrative Officer		■														
Recruitment of Research Officers and Research Assistants at hubs			■													
Recruitment of Research Officers at nodes				■												
Infrastructure plan																
Establishment of data base and website			■	■												
Establishment of laboratory space in collaboration with Universities and Medical Research Institutes			■	■												
Establishment of infrastructure - hubs				■												
Establishment of infrastructure - nodes					■											
Financial Plan																
Multi-Institutional Agreement including commitment of in-kind contributions			■	■												
Cost recovery system in place			■	■												
Sustainability plan development					■	■	■	■	■							
Operational Plan																
Protocol and ethics established			■	■	■											
Ethics established			■	■	■											
Consolidation of current brain banks			■	■	■											
Hubs fully operational					■											
Nodes fully operational							■									
Hub and node training						■										
Ongoing training opportunities for researchers and staff							■	■	■	■	■	■	■	■	■	■
Stakeholder engagement, review and improvement	■				■					■	■	■	■	■	■	■
Donor program established										■	■	■	■	■	■	■
Promotion activities initiated					■	■	■									
Report to stakeholders				■				■				■	■	■	■	■
Review and refinement of operations												■	■	■	■	■

Promotion

Promotion of the Australian Brain Bank is an essential component in honouring the commitments of donors and donor families, servicing the needs of stakeholders and ensuring financial sustainability. A key goal will be to increase the number of researchers using human tissue in their work and increase the variety of techniques being employed. The following key mechanisms of promotion will be put in place:

Development of a website and branding

A public facing website will be a key point of promotion to allow stakeholders and the community, both nationally and internationally, to find out more about the Australian Brain Bank, what it has to offer and its key activities. The website will be promoted through a number of avenues such as websites and newsletters of stakeholder organizations e.g. Dementia Australia, Australasian Neuroscience Society, ADNeT, Australian Biospecimen Network Association.

Engagement at national and international conferences

Researchers who access tissue from the Australian Brain Bank will be required to appropriately acknowledge the brain bank when reporting findings in published articles and at conferences. The development of a brand and logo will enable wide dissemination through the research community, especially at conference presentations.

As part of the marketing strategy, staff from the Australian Brain Bank will promote the brain bank at national and international conferences which are likely to attract key stakeholders. The brain bank will also consider strategies such as organizing and sponsoring symposia at meetings such as Australasian Neuroscience Society, DANDIS and Australian Dementia Forum, with the possibility of bringing international speakers with expertise in brain banking and/or using human tissue, particularly novel techniques. Researchers accessing the tissue as well as neuropathologists associated with the brain banks will be encouraged to present clinicopathological studies at these meetings.

Donor and Community Engagement and Education

It will be the responsibility of the Donor Program Coordinator to ensure public visibility of the Australian Brain Bank. Working with the Steering and Management Committees, they will develop a framework of community education to enable a better understanding in the community of the benefits of the brain bank and what the brain bank needs to maximize the benefits of donated brains. Close links between the community and the Australian Brain Bank are essential to encourage support and ensure quality. Public education may include public talks, newsletters and leaflets for distribution.

Listings on Key Websites

The Marketing and Communications Committee will ensure that the Australian Brain Bank is listed on key websites nationally and internationally, including but not limited to Alzforum, international brain bank websites and biobanking websites.

RISK MANAGEMENT FRAMEWORK

The following risk assessment table outlines the high-level project risks associated with the Australian Brain Bank. Individual level project risks will be identified and managed through existing processes such as Laboratory Standard Operating Procedures and Human Research Ethics Committee review processes.

Hierarchy of Control: Elimination, Substitution, Isolation, Engineering, Administration, Personal Protection

POTENTIAL RISKS	IMPACT OF RISKS	RISK CONTROL MEASURES
The Australian Brain Bank fails to become sustainable by year 5	The likely impact is that the brain bank would become fragmented, resulting in reduced capacity to meet needs of researchers and to honour commitments to donors and families	<ul style="list-style-type: none"> seek to diversify ongoing funding to include grants from governments and other bodies, cost recovery, in-kind contributions and philanthropic support commitment of in-kind support by a number of universities and medical research institutes across Australia
Cost recovery does not meet projected levels	This will lead to a shortfall in budget	<ul style="list-style-type: none"> realistic projection of cost recovery via benchmarking with equivalent international organizations and taking into account previous brain banking experience in Australia
A university or medical research institute ceases support for the brain bank	Reduced in-kind support such as laboratory space and potential loss of a hub or node	<ul style="list-style-type: none"> hubs and nodes approach makes loss of a hub unlikely due to ongoing support over many years by the institutions involved and the ability to move the brain bank assets to other institutions nodes can be flexible in their location depending on need
Lack of space and infrastructure as the program expands	Limited physical space and infrastructure to store brains so research is compromised	<ul style="list-style-type: none"> regular review of supply and demand of tissue monitoring of tissue stocks to dispose of tissue that is no longer useful prioritize brain collection to those samples that will be most useful for research amortisation of freezer cost in the budget plan including allowing for growth
Lack of neuropathology expertise	Reduced quality of research and inability to interpret data relative to work internationally	<ul style="list-style-type: none"> education and training will be a core activity including ensuring budgeting for expanded and ongoing neuropathology training
Academic integrity and scientific rigor not managed	Breaches of the Australian Code for the Responsible Conduct of Research and consequent reputational loss	<ul style="list-style-type: none"> ongoing yearly ethical review and monitoring at hubs and nodes

POTENTIAL RISKS	IMPACT OF RISKS	RISK CONTROL MEASURES
Brain Bank freezer failure	Loss of samples	<ul style="list-style-type: none"> all freezers in the hubs to be set with alarms to alert if they fail with a staff member responsible to respond to the alarms
Governance structure ineffective or inappropriate resulting in project milestones/budget not being appropriately set or managed	Projects may not meet milestones	<ul style="list-style-type: none"> establishment of a Steering Committee to provide independent strategic and scientific advice to the Management Committee to ensure accountability, expertise and stakeholder input
Exposure to infectious material	Staff at the brain bank or researchers using tissue may be exposed to infectious diseases transmitted to them from the tissue, resulting in disease or even death	<ul style="list-style-type: none"> procedures to exclude diseased tissue to be rigorously followed - high risk cases or cases suspected of having an infectious disease will be excluded from the collection all cases to be handled as being potentially infectious at all times - staff to take appropriate precautions and risk assessment (including hepatitis immune status verification) materials transfer agreements between the brain bank and researchers to highlight that it is the principal investigator's responsibility to undertake appropriate risk management for use of the tissue
Breach of privacy	Loss or reputation for the brain bank. Physical, mental or financial harm to the donor, researcher or other stakeholder	<ul style="list-style-type: none"> strict adherence to the privacy standards and legislation, with data de-identified and all staff involved trained in privacy requirements across all aspects of the business brain bank tissue and data to be stored in locked rooms or on password protected IT systems, with only authorized personnel having access

MONITORING PERFORMANCE

Performance and outcomes will be monitored against milestones identified for the establishment of the Australian Brain Bank and communicated to stakeholders in an annual report. Key performance indicators will also be set in place within the following categories and benchmarked against comparable international brain banks.

Governance

- evidence of robust decision processes
- evidence of strong engagement of stakeholders in Australian Brain Bank governance

Financial performance

- financial targets met
- audits demonstrate quality financial and risk management.

Research Infrastructure

- facilities and equipment are appropriate to size and scale of operations and well managed
- fit for purpose, as demonstrated by numbers and types of brains collected with respect to types of brains requested in applications
- value adding, as demonstrated by depth of phenotypic and clinical data available from donors before death and able to be accessed by research teams.

Meeting researcher needs

- breadth and relevance of the collection, as demonstrated by number and type of tissue applications
- strength of collaborations, as demonstrated by numbers of collaborating specialist brain collections
- researcher satisfaction, as evidenced via survey.

Engagement and training

- levels of attendance at events, seminars, conferences
- media presence
- numbers of donors
- donor and family member satisfaction.

Research Outputs

- number and quality of publications
- number of conference presentations
- value of grants secured where Australian Brain Bank samples have been required
- research breakthroughs achieved through research utilising Australian Brain Bank samples
- number, breadth and quality of national and international collaborations, including nature of collaboration
- publicly available research data made possible by the Australian Brain Bank.

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APPENDIX 1: BRAIN BANKING ACTIVITY IN AUSTRALIA

Active Brain Banks

- Victorian Brain Bank. Hosted at the Florey Institute of Neuroscience and Mental Health.*
- Sydney Brain Bank. Hosted at Neuroscience Research Australia and funded jointly by the University of New South Wales & Neuroscience Research Australia. *
- New South Wales Brain Tissue Resource Centre. Hosted at the University of Sydney. *
- Multiple Sclerosis Research Australia Brain Bank. Hosted at the University of Sydney.
- Australian Sports Brain Bank. Hosted at the Royal Prince Alfred Hospital.
- Western Australia Brain Bank. Hosted at the Royal Perth Hospital.

Inactive Brain Banks

- Queensland Brain Bank. Hosted at the University of Queensland.*
- South Australian Brain Bank. Hosted at Flinders University.*

Note: The Sydney Brain Bank and the New South Wales Tissue Resource Centre are members of the NSW Brain Banks, and there is an agreement between the three partner organisations through which they share common governance, a single tissue application process, shared standardised protocols and tissue fulfilment.

*members of the former Australian Brain Bank Network

APPENDIX 2: COST RECOVERY

Figures are based on the predicted operational costs, not including in-kind costs, in 2022, which is after the initial establishment of the Australian Brain Bank. The maximum tissue releases over the period of the grant (90) is used to calculate a cost based on a percentage cost recovery. Average number of tissue samples per tissue request is 160.⁽⁷⁾

Total cost per sample $\$2,074,136 / (90 \times 160) = \144

Cost recovery based on recovering 1/6, 1/5, 1/4 and 1/3 over years 2021-2024 would be \$24.00, \$28.80, \$36, and \$48 respectively

Note: Sample collection costs vary considerably and it is likely that the charges applied once the Australian Brain Bank is operational will reflect this cost variation. This cost recovery calculation facilitates modelling only and gains accuracy over time, and when applied to sufficiently large numbers of samples to account for this variation.

APPENDIX 3: FINANCIAL PROJECTIONS

Brain Banking Financial Projections		Year One (Implementation)			
		Unit cost	Qty.	In-kind contribution	Total
Central Administration					
Accommodation	Meeting/Office space costs/refurbishment		1	\$ 53,000.00	\$ 53,000.00
	General administration costs	\$ 4,000.00	1		\$ 4,000.00
Equipment	Website design and maintenance	\$ 25,000.00	1		\$ 25,000.00
	Computers	\$ 2,000.00	5		\$ 10,000.00
Database	Database infrastructure	\$ 100,000.00	1	\$ 50,000.00	\$ 150,000.00
Promotions	Conferences, international speakers, community		1	\$ 20,000.00	\$ 20,000.00
Travel	Travel budget		1	\$ 20,000.00	\$ 20,000.00
	Project Lead (FTE 1.0)	\$ 148,552.00	1		\$ 148,552.00
	Donor coordinator (FTE 1.0)	\$ 127,367.00	1		\$ 127,367.00
Personnel	Tissue Application coordinator (FTE 0.6 Yrs 1 & 2, FTE 1.0 Yrs 3 & 4)	\$ 127,367.00	0.6		\$ 76,420.20
	Database (IT) coordinator	\$ 127,367.00	1		\$ 127,367.00
	Consolidation project-staff travel and accommodation		1	\$ 5,000.00	\$ 5,000.00
	Initial recruitment costs		4	\$ 35,000.00	\$ 35,000.00
Contingency	Contingency (10%)	\$ 62,370.00	1		\$ 62,370.00
Sub-total		\$		\$ 183,000.00	\$ 864,076.20
Hubs					
Accommodation	Laboratory space ongoing cost including overheads & maintenance		2	\$ 300,000.00	\$ 300,000.00
	General administration costs	\$ 2,000.00	2		\$ 4,000.00
	Infrastructure equipment (computers etc.)	\$ 5,000.00	2		\$ 10,000.00
	Infrastructure equipment maintenance	\$ 25,000.00	2		\$ 50,000.00
Equipment	Freezers	\$ 20,000.00	2		\$ 40,000.00
	Software	\$ 2,000.00	2		\$ 4,000.00
	Lab consumables-fresh tissue processing	\$ 60.00	110		\$ 6,600.00
	Lab consumables - tissue applications	\$ 20.00	70		\$ 1,400.00
Transport	Cost to transport donor to/from mortuary & tissue from mortuary	\$ 1,000.00	110		\$ 110,000.00
Neuropathology	Macro/micro examination consumables, histology, routine staining , IHC	\$ 950.00	110		\$ 104,500.00
	Neuropathologists			\$ 138,112.00	\$ 138,112.00
	Neuropathologist training (FTE 0.2)	\$ 170,655.00	0.4		\$ 68,262.00
	Hub 1 lead (FTE 1.0)	\$ 127,367.00	1		\$ 127,367.00
Personnel	Hub 2 lead (FTE 1.0)	\$ 127,367.00	1		\$ 127,367.00
	Research Officer (FTE 1.0 each site)	\$ 127,367.00	2		\$ 254,734.00
	Research Assistant (FTE 0.4 Yrs 1 & 2 FTE 0.6 Yrs 3 & each site)	\$ 101,500.00	0.8		\$ 81,200.00
	Mortuary services	\$ 900.00	110		\$ 99,000.00
Contingency	Contingency (10%)	\$ 108,843.00	1		\$ 108,843.00
Sub-total		\$		\$ 438,112.00	\$ 1,635,385.00
Nodes					
Accommodation	Laboratory space ongoing cost including overheads, maintenance		4	\$ 150,000.00	\$ 150,000.00
	General administration costs	\$ 1,000.00	4		\$ 4,000.00
	Infrastructure equipment (computers, cameras, mobiles etc.)	\$ 4,000.00	4		\$ 16,000.00
Equipment	Infrastructure equipment maintenance	\$ 5,000.00	0		\$ -
	Freezers	\$ 20,000.00	4		\$ 80,000.00
	Software	\$ 2,000.00	4		\$ 8,000.00
	Lab consumables	\$ 60.00	0		\$ -
Transport	Cost to transport donor to/from mortuary & tissue from mortuary	\$ 1,000.00	0		\$ -
	Cost to transport tissue to hubs	\$ 700.00	0		\$ -
	Node leads (X4) (FTE 0.6 each site) (Yr 1 last quarter only)	\$ 101,500.00	0.6		\$ 60,900.00
Personnel	Mortuary services	\$ 900.00	0		\$ -
	Staff training	\$ 1,500.00	4		\$ 6,000.00
Contingency	Contingency (10%)	\$ 17,490.00	1		\$ 17,490.00
Sub-total		\$		\$ 150,000.00	\$ 342,390.00
TOTALS		\$ 1,699,202.00		\$ 771,112.00	\$ 2,841,851.20

Brain Banking Financial Projections		Year Two			
		Unit cost	Qty.	In-kind contribution	Total
Central Administration					
Accommodation	Meeting/Office space costs/refurbishment		1	\$ 54,060.00	\$ 54,060.00
	General administration costs	\$ 4,080.00	1		\$ 4,080.00
Equipment	Website design and maintenance	\$ 2,000.00	1		\$ 2,000.00
	Computers		0		
Database	Database infrastructure		1	\$ 10,000.00	\$ 10,000.00
Promotions	Conferences, international speakers, community		1	\$ 20,400.00	\$ 20,400.00
Travel	Travel budget		1	\$ 20,400.00	\$ 20,400.00
	Project Lead (FTE 1.0)	\$ 151,523.04	1		\$ 151,523.04
	Donor coordinator (FTE 1.0)	\$ 129,914.34	1		\$ 129,914.34
Personnel	Tissue Application coordinator (FTE 0.6 Yrs 1 & 2, FTE 1.0 Yrs 3 & 4)	\$ 129,914.34	0.6		\$ 77,948.60
	Database (IT) coordinator	\$ 129,914.34	0.2		\$ 25,982.87
	Consolidation project-staff travel and accommodation		0		\$
	Initial recruitment costs		0		\$
Contingency	Contingency (10%)	\$ 37,104.00	1		\$ 37,104.00
Sub-total				\$ 104,860.00	\$ 513,012.85
Hubs					
Accommodation	Laboratory space ongoing cost including overheads & maintenance		2	\$ 306,000.00	\$ 306,000.00
	General administration costs	\$ 2,040.00	2		\$ 4,080.00
	Infrastructure equipment (computers etc.)		0		\$
	Infrastructure equipment maintenance	\$ 25,500.00	2		\$ 51,000.00
Equipment	Freezers	\$ 20,400.00	2		\$ 40,800.00
	Software	\$ 2,040.00	2		\$ 4,080.00
	Lab consumables-fresh tissue processing	\$ 61.20	115		\$ 7,038.00
	Lab consumables - tissue applications	\$ 20.40	75		\$ 1,530.00
Transport	Cost to transport donor to/from mortuary & tissue from mortuary	\$ 1,020.00	115		\$ 117,300.00
Neuropathology	Macro/micro examination consumables, histology, routine staining , IHC	\$ 969.00	150		\$ 145,350.00
	Neuropathologists			\$ 139,034.00	\$ 139,034.00
	Neuropathologist training (FTE 0.2)	\$ 174,068.00	0.4		\$ 69,627.20
	Hub 1 lead (FTE 1.0)	\$ 129,914.34	1		\$ 129,914.34
Personnel	Hub 2 lead (FTE 1.0)	\$ 129,914.34	1		\$ 129,914.34
	Research Officer (FTE 1.0 each site)	\$ 129,914.34	2		\$ 259,830.00
	Research Assistant (FTE 0.4 Yrs 1 & 2 FTE 0.6 Yrs 3 & each site)	\$ 103,530.00	0.8		\$ 82,824.00
	Mortuary services	\$ 918.00	110		\$ 105,570.00
Contingency	Contingency (10%)	\$ 114,885.00	1		\$ 114,885.00
Sub-total				\$ 445,034.00	\$ 1,708,776.88
Nodes					
Accommodation	Laboratory space ongoing cost including overheads, maintenance		4	\$ 153,000.00	\$ 153,000.00
	General administration costs	\$ 1,020.00	4		\$ 4,080.00
	Infrastructure equipment (computers, cameras, mobiles etc.)		0		\$
Equipment	Infrastructure equipment maintenance	\$ 5,000.00	2		\$ 10,000.00
	Freezers		0		\$
	Software	\$ 2,040.00	4		\$ 8,160.00
	Lab consumables	\$ 61.20	35		\$ 2,142.00
Transport	Cost to transport donor to/from mortuary & tissue from mortuary	\$ 1,020.00	35		\$ 35,700.00
	Cost to transport tissue to hubs	\$ 714.00	35		\$ 24,990.00
	Node leads (X4) (FTE 0.6 each site) (Yr 1 last quarter only)	\$ 105,530.00	2.4		\$ 248,472.00
Personnel	Mortuary services	\$ 918.00	35		\$ 32,130.00
	Staff training		0		\$ 6,000.00
Contingency	Contingency (10%)	\$ 36,567.00	1		\$ 17,490.00
Sub-total				\$ 153,000.00	\$ 555,241.00
TOTALS				\$ 702,894.00	\$ 2,777,030.73

Brain Banking Financial Projections		Year Three			
		Unit cost	Qty.	In-kind contribution	Total
Central Administration					
Accommodation	Meeting/Office space costs/refurbishment		1	\$ 55,141.20	\$ 55,141.20
	General administration costs	\$ 4,161.60	1		\$ 4,161.60
Equipment	Website design and maintenance	\$ 2,040.00	1		\$ 2,040.00
	Computers		0		
Database	Database infrastructure		1	\$ 10,200.00	\$ 10,200.00
Promotions	Conferences, international speakers, community		1	\$ 20,808.00	\$ 20,808.00
Travel	Travel budget		1	\$ 20,808.00	\$ 20,808.00
	Project Lead (FTE 1.0)	\$ 154,553.50	1		\$ 154,553.50
	Donor coordinator (FTE 1.0)	\$ 132,512.63	1		\$ 132,512.63
Personnel	Tissue Application coordinator (FTE 0.6 Yrs 1 & 2, FTE 1.0 Yrs 3 & 4)	\$ 132,512.63	1		\$ 132,512.63
	Database (IT) coordinator	\$ 132,512.63	0.2		\$ 26,502.53
	Consolidation project-staff travel and accommodation		0		\$
	Initial recruitment costs		0		\$
Contingency	Contingency (10%)	\$ 45,228.00	1		\$ 45,228.00
Sub-total				\$ 104,860.00	\$ 513,012.85
Hubs					
Accommodation	Laboratory space ongoing cost including overheads & maintenance		2	\$ 312,120.00	\$ 312,120.00
	General administration costs	\$ 2,080.00	2		\$ 4,160.00
	Infrastructure equipment (computers etc.)		0		\$
	Infrastructure equipment maintenance	\$ 26,010.00	2		\$ 51,000.00
Equipment	Freezers	\$ 20,808.00	2		\$ 40,800.00
	Software	\$ 2,080.00	2		\$ 4,080.00
	Lab consumables-fresh tissue processing	\$ 62.42	115		\$ 7,038.00
	Lab consumables - tissue applications	\$ 20.80	75		\$ 1,530.00
Transport	Cost to transport donor to/from mortuary & tissue from mortuary	\$ 1,040.00	115		\$ 117,300.00
Neuropathology	Macro/micro examination consumables, histology, routine staining , IHC	\$ 988.00	150		\$ 145,350.00
	Neuropathologists			\$ 139,975.00	\$ 139,034.00
	Neuropathologist training (FTE 0.2)	\$ 177,549.00	0.4		\$ 69,627.20
	Hub 1 lead (FTE 1.0)	\$ 132,512.63	1		\$ 129,914.34
Personnel	Hub 2 lead (FTE 1.0)	\$ 132,512.63	1		\$ 129,914.34
	Research Officer (FTE 1.0 each site)	\$ 132,515.00	2		\$ 259,830.00
	Research Assistant (FTE 0.4 Yrs 1 & 2 FTE 0.6 Yrs 3 & each site)	\$ 105,600.00	1.2		\$ 82,824.00
	Mortuary services	\$ 936.00	120		\$ 105,570.00
Contingency	Contingency (10%)	\$ 114,885.00	1		\$ 114,885.00
Sub-total				\$ 452,095.00	\$ 1,815,044.25
Nodes					
Accommodation	Laboratory space ongoing cost including overheads, maintenance		4	\$ 156,060.00	\$ 156,060.00
	General administration costs	\$ 1,040.00	4		\$ 4,160.00
	Infrastructure equipment (computers, cameras, mobiles etc.)		0		\$
Equipment	Infrastructure equipment maintenance	\$ 5,100.00	2		\$ 10,200.00
	Freezers		0		\$
	Software	\$ 2,080.00	4		\$ 8,320.00
	Lab consumables	\$ 62.42	45		\$ 2,808.90
Transport	Cost to transport donor to/from mortuary & tissue from mortuary	\$ 1,040.00	45		\$ 46,800.00
	Cost to transport tissue to hubs	\$ 728.00	45		\$ 32,760.00
	Node leads (X4) (FTE 0.6 each site) (Yr 1 last quarter only)	\$ 105,600.00	2.4		\$ 253,440.00
Personnel	Mortuary services	\$ 936.00	45		\$ 42,120.00
	Staff training		0		\$
Contingency	Contingency (10%)	\$ 40,360.00	1		\$ 40,360.00
Sub-total				\$ 156,060.00	\$ 597,028.90
TOTALS				\$ 715,112.20	\$ 3,016,541.24

Brain Banking Financial Projections		Year Four			
		Unit cost	Qty.	In-kind contribution	Total
Central Administration					
Accommodation	Meeting/Office space costs/refurbishment		1	\$ 56,244.02	\$ 56,244.02
	General administration costs	\$ 4,244.83	1		\$ 4,244.83
Equipment	Website design and maintenance	\$ 2,080.80	1		\$ 2,080.80
	Computers		0		
Database	Database infrastructure		1	\$ 10,404.00	\$ 10,404.00
Promotions	Conferences, international speakers, community		1	\$ 21,224.16	\$ 21,224.16
Travel	Travel budget		0		\$ 21,224.16
	Project Lead (FTE 1.0)	\$ 157,644.57	1		\$ 157,644.57
	Donor coordinator (FTE 1.0)	\$ 135,162.88	1		\$ 135,162.88
Personnel	Tissue Application coordinator (FTE 0.6 Yrs 1 & 2, FTE 1.0 Yrs 3 & 4)	\$ 135,162.88	1		\$ 135,162.88
	Database (IT) coordinator	\$ 135,162.88	0.2		\$ 27,032.58
	Consolidation project-staff travel and accommodation		0		\$
	Initial recruitment costs		0		\$
Contingency	Contingency (10%)	\$ 46,132.00	1		\$ 46,132.00
Sub-total				\$ 109,096.34	\$ 616,556.88
Hubs					
Accommodation	Laboratory space ongoing cost including overheads & maintenance		2	\$ 318,362.40	\$ 318,362.40
	General administration costs	\$ 2,122.00	2		\$ 4,244.00
	Infrastructure equipment (computers etc.)		0		\$
	Infrastructure equipment maintenance	\$ 26,530.00	2		\$ 53,060.00
Equipment	Freezers	\$ 21,225.00	2		\$ 42,450.00
	Software	\$ 2,122.00	2		\$ 4,244.00
	Lab consumables-fresh tissue processing	\$ 63.67	125		\$ 7,958.75
	Lab consumables - tissue applications	\$ 21.20	90		\$ 1,908.00
Transport	Cost to transport donor to/from mortuary & tissue from mortuary	\$ 1,061.00	125		\$ 132,625.00
Neuropathology	Macro/micro examination consumables, histology, routine staining , IHC	\$ 1,008.00	185		\$ 186,480.00
	Neuropathologists			\$ 140,934.00	\$ 140,934.00
	Neuropathologist training (FTE 0.2)	\$ 181,100.00	0.4		\$ 72,440.00
	Hub 1 lead (FTE 1.0)	\$ 135,162.88	1		\$ 135,162.88
Personnel	Hub 2 lead (FTE 1.0)	\$ 135,162.88	1		\$ 135,162.88
	Research Officer (FTE 1.0 each site)	\$ 135,520.00	2		\$ 265,040.00
	Research Assistant (FTE 0.4 Yrs 1 & 2 FTE 0.6 Yrs 3 & each site)	\$ 107,713.00	1.2		\$ 129,255.60
	Mortuary services	\$ 955.00	125		\$ 119,375.00
Contingency	Contingency (10%)	\$ 128,940.00	1		\$ 128,940.00
Sub-total				\$ 459,296.40	\$ 1,877,642.51
Nodes					
Accommodation	Laboratory space ongoing cost including overheads, maintenance		4	\$ 159,181.20	\$ 159,181.20
	General administration costs	\$ 1,061.00	4		\$ 4,244.00
	Infrastructure equipment (computers, cameras, mobiles etc.)		0		\$
Equipment	Infrastructure equipment maintenance	\$ 5,202.00	2		\$ 10,404.00
	Freezers		0		\$
	Software	\$ 2,122.00	4		\$ 8,488.00
	Lab consumables	\$ 63.67	60		\$ 3,820.20
Transport	Cost to transport donor to/from mortuary & tissue from mortuary	\$ 1,061.00	60		\$ 63,660.00
	Cost to transport tissue to hubs	\$ 743.00	60		\$ 32,760.00
	Node leads (X4) (FTE 0.6 each site) (Yr 1 last quarter only)	\$ 105,600.00	2.4		\$ 258,508.80
Personnel	Mortuary services	\$ 955.00	60		\$ 57,300.00
	Staff training		0		\$
Contingency	Contingency (10%)	\$ 45,090.00	1		\$ 45,090.00
Sub-total				\$ 159,181.20	\$ 655,276.00
TOTALS				\$ 727,573.94	\$ 3,149,475.39

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Key contributors to this proposal and business case are listed below.

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