



Victorian Brain Bank

Guidelines for Researchers

The Victorian Brain Bank is funded in part by The Florey, Fight Parkinson's, FightMND, Ian and Maria Cootes and One More Night for Tania.

Version 12 Revised March 2024

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INTRODUCTION

The Victorian Brain Bank (VBB) is located at The Florey and is a research resource facility that provides Australian and International researchers with easy access to well-characterised postmortem human central nervous system (CNS) tissues on which researchers can conduct analyses related to their fields of endeavour.

The operations of the VBB are under the jurisdiction of the Human Research Ethics Committee of The University of Melbourne and the Victorian Institute of Forensic Medicine.

CASES AVAILABLE

Tissues available include cases with dementia, movement disorders, psychiatric disorders, neurotrauma and normal 'controls'. All cases are clinically and neuropathologically characterised. The tissue is suitable for but not limited to genomics, neuroanatomical, neuropathological, neuropharmacological and neurochemistry studies.

ACCESSING TISSUE FROM THE VBB

Initial enquiry

Researchers can enquire about obtaining tissue by contacting VBB research assistant, Tom Allen on 03 8344 1900 or at <u>VictorianBrainBank@Florey.edu.au</u>.

Each enquiry will be reviewed to ascertain the availability of tissue. If the enquiry is feasible the researcher will be made aware of the VBB policy on fee for service and the need for a Material Transfer Agreement (MTA) to be signed following approval of a tissue request.

Once these items have been discussed and agreed by the researcher, a tissue application will be sent to the researcher.

Please ensure the Principal Investigator (PI) submits the application. For student projects, the supervisor or post-doctoral researcher with relevant expertise in the area is responsible for submitting the application. The PI will need to submit a biosketch, which will be used to assess their expertise and ability to undertake the research.

Trial tissue enquiry

Provision of limited 'trail' tissue for the purpose of developing new techniques or gaining preliminary data for power analyses can be accessed. This tissue is from cases that do not meet diagnostic criteria. Outcome report from the trail tissue is required in a timely manner before proceeding to a full tissue application. It would not be expected that data from trial tissue would be suitable for publication.

Letter of support enquiry

Provision of a letter of support to confirm availability of tissue and estimated cost of access can be provided to granting bodies.

REQUESTING TISSUE

Important considerations when requesting tissue for your project:

- Region/s of tissue required and justification.
- Total number of cases required for statistical analysis. It is highly recommended that a power analysis based on reasonable assumptions is included.
- Type/s of tissue requested and justification i.e. fresh frozen, formalin fixed, paraffin embedded sections or cerebrospinal fluid.

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 Amount of tissue requested with justification of weight or number of sections based on preliminary work (eg. yields of extracts protein, RNA, number of stains).

The type and amount of tissue requested must accurately reflect what is required to complete the project using the methodology described.

The PI responsible for the application must have obtained Human Research Ethics Committee (HREC) approval for the specified scientific project from their parent institution before submitting an application. All people involved in the project, including students, must be named on the HREC approval. A letter of approval in English from the HREC of the applicant's parent institution must be made available prior to the tissue being provided for the research project.

Applicants must answer all questions and the PI must sign the application and return it to the VBB coordinator. All applications are reviewed by the VBB Scientific Review Committee (SRC) which comprises of VBB members and independent specialist scientists. The provision of tissue to the applicant will be based on scientific merit and feasibility of the research proposals.

On approval of the application, it is obligatory to sign the MTA before the tissue will be provided. If the project requires tissue to be sent to investigator/s at other institution/s (details of which must be included in the tissue application), an MTA/s must also be signed.

A discussion between applicants and the VBB at any time during the application process is encouraged as the VBB personnel can provide useful advice and expertise on the use of human tissue and availability of tissue.

RESOURCE LIMITATIONS

Applicants must accept that decisions regarding the supply of tissue will be made in the light of overall demands placed on the VBB and the impact on these demands on available tissue.

Applications may need to be modified before submission, depending on disease category, region and amount of tissue available.

To minimise wastage and maximise the use of tissue and allow more than one research group to access the same brain region of a particular case, tissue sections (fresh frozen or formalin fixed) mounted on glass slides are available, in preference to blocks of tissue.

If the VBB is unable to completely fill your request, we would like to share your request with other Australian Brain Banks in order to complete your request; this would only be done with the researcher permission.

HANDLING RISKS AND SAFETY PRECAUTIONS

The VBB is aware of the dangers and risks to themselves and researchers from potentially infectious post-mortem human material and therefore any tissue supplied is on the understanding that experiments performed will be undertaken in appropriate facilities. The VBB accepts no responsibility for the transmission of any disease or injury as a result of the use of any materials supplied. While every effort is made to exclude infectious cases, the VBB cannot guarantee that cases are not infectious. We would like to highlight the importance of handling human tissue as being potentially infectious at all times. High risk cases or cases suspected of having an infectious disease are excluded from the collection.

It is the PI responsibility to ensure all staff comply with handling and storage procedures of their institution/s and that adequate safety information and necessary training is provided to co-

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Approved by: Fairlie Hinton Date: 15 June 2023 investigators and students handling the tissues. It is recommended that all person working with human tissue have their hepatitis immune status verified and undergo vaccination, if necessary.

USE OF TISSUE

The tissue provided must only be used solely for the project identified in the Tissue Request Application. Any proposed modification to an approved project must be communicated in writing to the VBB and the modification approved by the SRC prior to using the modified tissue protocol.

The tissue provided is for the exclusive use of the PI and acknowledged co-investigators and students named on the application.

Any tissue transferred from the VBB to the recipients remains under the control of the VBB. The recipients have only a non-exclusive right to use the tissue within the terms of the agreement. Consistent with this non-exclusive right, the recipients are not permitted to sell, loan or otherwise provide the tissues to a third party without prior written consent from the VBB.

Tissues to be disposed of that cannot be returned to the VBB must be handled in an ethical and respectful manner, in accordance with prevailing State regulations.

AMENDMENTS

An amendment to the original Tissue Request Application may be submitting to the VBB Coordinator where researchers want to:

- 1) Notify the VBB about additional researchers or when an investigator who is using the tissue moves to a different institution.
- 2) Request additional tissue for studies that are within the scientific scope and aims of the original request and are necessary for the completion and publication of the original study. Should a request for an amendment propose significant changes to the procedures (i.e., different brain regions or disease categories) or fall outside the scope of the original HREC approved application, a new tissue application will be required.
- 3) Request permission to use remaining tissue, for studies that are within the scientific scope and aims of the original request.
- 4) Request permission to use remaining tissue, for purposes other than those described in the original application, a new tissue application will be required.

If you are unsure about whether the applications fits the amendment criteria please contact the VBB coordinator. If the original application was approved more than 5 years prior, please discuss the application with the VBB coordinator prior to submission.

CASE INFORMATION

The information available to researchers includes age, gender, post-mortem interval, cause of death, disease duration, fresh tissue pH and neuropathological disease classification. Any additional clinical information must be included in the tissue application and incurs an additional access fee.

Applicants have access to the tissue and clinical information only through a unique identifier assigned by the VBB to ensure confidentiality is maintained.

On receipt of the tissue, researchers <u>MUST</u> issue new unique identification numbers for each case. No original VBB unique identifiers are to be published.

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Version: v11 Modified June 2023

ACCESS RATES AND TRANSPORT COSTS

A fee for service is necessary to offset the considerable expenditure by the VBB for the personnel and operational costs associated with collection, processing, characterisation and storing the tissue as well as data management and quality assurance systems.

Access rates for services are in accordance with the National Access Policy (as per Enabling Grant Access to Facilities Policy-2005) and are reviewed annually and may change without notice.

Please contact the VBB Coordinator to obtain an estimated service fee prior to submitting any grant applications to fund a project requiring human brain tissue from the VBB.

All transport costs for the delivery of the tissue are the responsibility of the recipient and should also be included as a budget item in grant applications requiring tissue from the VBB. The PI and their institute are also responsible for complying with appropriate customs and other regulations for the transportation and importing of human tissue within or from Australia. The PI is also responsible for any transport costs associated with returning unused tissue to the VBB.

ACKNOWLEDGMENT

As part of the application approval process the SRC will discuss each project and will make a recommendation regarding whether the tissue request justifies seeking authorship or whether acknowledgement of the VBB is sufficient. Additional clinical information and/or pathological information may require authorship.

If significant intellectual input during the data analysis process is required from VBB members, it is possible that active collaboration and resulting authorship that were not planned during the initial submission may arise.

The VBB must be acknowledged in all oral and written presentations and publications arising from the use of tissue even where the absence of agreed collaborations means that members of the VBB are not authors on any presentations or publication. Failure to comply with this requirement will jeopardise future access to VBB tissue.

For publications using tissue accessed from the VBB the following wording must be used: 'Brain tissues were received from the Victorian Brain Bank, in part funded by The Florey, Fight Parkinson's, FightMND, Ian and Maria Cootes and One More Night for Tania'

For abstracts where space is limited the following acknowledgment statement should appear: 'Tissue from Victorian Brain Bank or VBB'.

MATERIAL TRANSFER AGREEMENT

A Material Transfer Agreement (MTA) must be signed by the Recipient Institution Authorized Delegate and Recipient Principal Investigator before the tissue/s are provided.

If a project requires tissue and or derivatives to be sent to investigator/s at other institution/s (details of which must be provided in the tissue application) an MTA must also be signed.

In signing the agreement, you are signifying that you have read and understood your responsibilities on receipt of the material as outlined in this document.

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Approved by: Fairlie Hinton Date: 15 June 2023

Version: v11 Modified June 2023

REPORT REQUIREMENTS

The PI must provide an annual report on the progress and outcomes of the project including publications, scientific presentations and press resulting from the use of the VBB tissue. Annual reports are required until the completion of the project and all outcomes have been published.

An audit will be performed annually to identify users who have not returned their reports and closed projects with no research outcomes.

VBB CONTACT DETAILS

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DONOR ACKNOWLEDGEMENT

The VBB would like to acknowledge the generosity shown by the donor and donor families in donating tissue for research into brain and mind disorders. It is an act of great foresight and kindness to give at a time of loss, so that others may be helped in the future.

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Version: v11 Modified June 2023