



Victorian Brain Bank

Guidelines for Researchers

The Victorian Brain Bank is funded in part by Parkinson's Victoria, MND Victoria, FightMND and Yulgilbar Foundation.

Victorian Brain Bank in collaboration with the The Florey Institute of Neuroscience and Mental Health, Motor Neurone Disease Research Tissue Bank, MS Research Australia, Victorian Institute of Forensic Medicine and The Alfred.

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INTRODUCTION

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

Operation of the VBB is 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 genomics, neuroanatomical, neuropathological, neuropharmacological and neurochemistry studies.

TISSUE ACCESS ENQUIRIES

Initial enquiry

Researchers can enquire about obtaining tissue by contacting the VBB coordinator, Fairlie Hinton on 03 8344 1900 or at fairlie.hinton@florey.edu.au.

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 cost recovery and the need for a Material Transfer Agreement.

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

Please ensure the Principal Investigator submits the application. For student projects, the supervisor or post-doctoral researcher is responsible for submitting the application.

Trial tissue enquiry

For the purpose of developing new techniques or gaining preliminary data for power analyses limited 'trial' tissue can be accessed. This tissue is from cases that do not meet diagnostic criteria. Outcome report from the trial tissue is requested before proceeding to a full tissue application.

Letter of support enquiry

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.
- Amount of tissue requested with justification of weight or number of sections based on preliminary work such as 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 principal investigator 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 persons involved in the project, including students, must be named on the HREC application. 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 Principal Investigator must sign the application and return 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 Material Transfer Agreement (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.

Amendments

Amendments to the original Tissue Request Application may be made by submitting an Amendment of an Existing Project, contact the VBB Coordinator.

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 you must complete a new full application.

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, dependent on disease category, region and amount of tissue available.

In order 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 potential 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 uses of any materials supplied. While every effort is made to exclude infectious cases, the VBB cannot guarantee that all cases are not infectious, so therefore **we recommend all cases be handled 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 Principal Investigator 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-investigators and students handling the tissues. It is recommended that all staff handling 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 on the Tissue Request Application. Any proposed modification from the agreed protocol 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 Principal Investigator 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.

Tissue 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.

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 must issue new unique identification numbers for each case. No original VBB unique identifiers are to be published.

ACCESS RATES AND TRANSPORT COSTS

Some cost recovery is necessary to offset the considerable expenditure by the VBB for the personnel and consumables necessary to collect, process, characterise and store the tissue as well as data management and quality assurance systems.

Access rates for services are in accordance to the National Access Policy and are reviewed annually and may change without notice.

Please contact the VBB Coordinator to obtain an estimate for cost recovery 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 for the VBB. The Principal Investigator 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 Principal Investigator 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, supported by The Florey, The Alfred and the Victorian Institute of Forensic Medicine and funded in part by Parkinson's Victoria, MND Victoria, FightMND and Yulgilbar Foundation'*.

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

MATERIAL TRANSFER AGREEMENT

Material Transfer Agreement must be signed by the Recipient Institution Authorized Delegate and Recipient Principal Investigator before the tissue/s will be provided. See attachment 1- Sample Material Transfer Agreement (MTA).

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.

REPORT REQUIREMENTS

The Principal Investigator 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

Director

Professor Catriona McLean
C.McLean@alfred.org.au
+61 3 9276 3153

Specialty area: neurodegenerative, neurotrauma and control cases.

Deputy Director

Professor Brian Dean
brian.dean@florey.edu.au
+61 3 8344 3786

Specialty area: psychiatric cases.

VBB Coordinator

Ms Fairlie Hinton
fairlie.hinton@florey.edu.au
+61 3 8344 1900

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.



ATTACHMENT 1 – SAMPLE MATERIAL TRANSFER AGREEMENT

SAMPLE MATERIAL TRANSFER AGREEMENT – Attachment 1

This Agreement (the "**Agreement**") is made effective as of the Click or tap here to enter text. day of Click or tap here to enter text. 2019, by and between Click or tap here to enter text. an organisation with an address of Click or tap here to enter text. ("**Recipient**") through the Principal Investigator Click or tap here to enter text. ("**PI**")

and;

The Florey Institute of Neuroscience and Mental Health, ABN 92 124 762 027, on behalf of the **Victorian Brain Bank**, with an address of Level 5, Kenneth Myer Building, 30 Royal Parade, Parkville, Victoria 3052 ("**VBB**").

Now, therefore, in consideration of the covenants, terms and conditions hereinafter expressed, VBB and Recipient agree as follows:

VBB is providing to Recipient, through the PI the proprietary biological materials, clinical and demographic data ("**Materials**") of the following description: **Post Mortem Central Nervous system tissue samples with the designation:**

1. Click or tap here to enter text.
2. Click or tap here to enter text.

VBB is providing the Materials to Recipient on the following conditions:

1. VBB will not issue any Material to Recipient without VBB having first received a letter of approval from the Recipients Human Research Ethics for the research project.
2. The Recipient acknowledges that they have received; read and understood the "Guidelines for Researchers" (attached hereto and titled 'Annexure 1').
3. Recipient agrees that on receipt of the Materials new identification numbers must be issued for each case. The Recipient agrees that no original VBB unique identifiers are to be published.
4. This Agreement will commence on the date the last party signs this Agreement ("Commencement Date") and will expire five calendar years from the Commencement Date ("Initial Term".) Unless agreed otherwise agreed in writing, this Agreement shall automatically renew for a further five year term ("Further Term") after expiration of the Initial Term.
5. VBB accepts no responsibility and no liability to the Recipient whatsoever (whether in contract, tort including negligence, pursuant to statute or otherwise) for any injury (including injury resulting in death), damage or any loss of profits, liability to any third party, or any indirect or consequential loss or damage arising from the use of these Materials by the Recipient or in relation to this Agreement.



ATTACHMENT 1 – SAMPLE MATERIAL TRANSFER AGREEMENT

6. Recipient assumes all responsibilities and risks in connection with the receipt, handling, storage, and use of these Materials by the recipient. Use of the Materials will be in compliance with all applicable federal, state, and local laws and regulations.
7. Recipient understands that these Materials have not been approved for human use and agrees that the Materials will not be administered to humans in any manner or form.
8. The Materials provided hereunder are experimental in nature, and are provided WITHOUT WARRANTY, EXPRESS OR IMPLIED, INCLUDING WITHOUT LIMITATION, WARRANTY OF MERCHANTABILITY OR FITNESS FOR A PARTICULAR PURPOSE AND WITHOUT WARRANTY THAT THE USE OF THE MATERIAL WILL NOT INFRINGE ANY PATENT OR OTHER PROPRIETARY RIGHT OF A THIRD PARTY.
9. Recipient agrees that these Materials will be used exclusively for non-commercial research purposes only and solely for the purpose outlined in **The Tissue Request Application number: VBB No. XX.XX**.
10. These Materials are considered proprietary and are, and at all times remain, the sole property of VBB.
11. These Materials are not to be sold, transferred or otherwise distributed to any third party for any purpose without the prior written permission of VBB.
12. The furnishing of Material under this Agreement shall not constitute any grant, option or license to Recipient under any patent or other rights now or hereafter held by VBB.
13. Any unused quantities of the Material will be disposed of according to prescribed federal, state and local guidelines or at VBB's request, will be destroyed by Recipient. Recipient agrees to formally notify VBB within 60 days that the Material has been destroyed in accordance with this clause 10.
14. The recipient may publish any outcomes of research that are derived for the use of the Materials. Recipient agrees to provide VBB with a copy of any publications, whether oral or written prior to the date of the proposed submission or presentation. Recipient further agrees to acknowledge the Victorian Brain Bank as the provider of the Material in any publication using the following language and in accordance with the authorship guidelines in section 5 of the Australian Code for Responsible Conduct of Research (2007):

All publications using tissue accessed from the **VBB**, the recipient agrees to cite the VBB in the 'material and methods' and 'acknowledgment' sections. The following wording must be used: *'Tissues were received from the Victorian Brain Bank, supported by The Florey Institute of Neuroscience and Mental Health, The Alfred and the Victorian Forensic Institute of Medicine and funded in part by Parkinson's Victoria, MND Victoria, FightMND and Yulgilbar Foundation.*

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

15. Recipient agrees to provide to VBB an annual progress report and a listing of all publications, presentations and press arising from the use of VBB tissue for the Term of this Agreement.



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16. VBB may terminate this agreement at any time by giving 30 days written notice to the Recipient Organisation. In accordance with clause 14, VBB may require that any remaining tissue is destroyed following termination of this Agreement.
17. This agreement may only be amended in writing, signed by the parties. If any provision of this agreement is invalid or unenforceable, it will be deemed deleted but the remaining provisions of this agreement will remain in full force and effect.
18. This Agreement shall be interpreted and enforced in accordance with the laws of Victoria, Australia.
19. This Agreement constitutes the entire agreement and understanding between the parties with respect to the subject matter herein and supersedes any prior agreements or understanding, written or oral, relating to the subject matter of this Agreement. This Agreement may be modified or amended only by a written instrument signed by all parties to this Agreement.

(a) **VBB**

Mr Peter Plecher
Chief Operating Officer

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Level 5, Kenneth Myer Building
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The University of Melbourne, Victoria, Australia 3010
Tel: +61 3 9035 4754
Fax: +61 3 9035 3105
Mobile: +61438 019 088
Email: peter.plecher@florey.edu.au

(b) **RECIPIENT** - (Authorized delegate)

Name: Click or tap here to enter text.
Address: Click or tap here to enter text.
Tel: Click or tap here to enter text.
Email: Click or tap here to enter text.

AGREED TO AND ACCEPTED BY AN AUTHORISED SIGNATORY OF:

The Florey Institute of Neuroscience and Mental Health:

Signature: _____

Name: _____

Position title: _____

Date: _____



ATTACHMENT 1 – SAMPLE MATERIAL TRANSFER AGREEMENT

AND RECIPIENT: Click or tap here to enter text. [[Insert Organization's name here](#)]

Signature: _____ (Authorised delegate)

Name: _____

Position title: _____

Date: _____

AND HAVING BEEN READ AND ACKNOWLEDGED BY

PRINCIPAL INVESTIGATOR:

Name: _____

Position title: _____

Date: _____