How to Apply and Conditions of Use

1. How To Apply

1.1. The Victorian Cancer Biobank (VCB) is a not-for-profit organisation funded by the Victorian Government and the generous support of our participating institutions. The VCB is an open-access platform available to all researchers who have Human Research Ethics Committee (or equivalent) approval for their study.

1.2. Applying to the VCB requires the completion of two forms: **General Application Form (Part A) and Application for Biospecimens or Services (Part B)**.

1.3. Before applying researchers are encouraged to check with the VCB Applications Manager for the availability of data and biospecimens: VCBEnquiries@cancervic.org.au

1.4. Application Forms A and B can be returned to: VCBApplications@cancervic.org.au

2. Acknowledgement and Reporting Policy

2.1. The VCB requires that a list of abstracts, publications and presentations resulting from materials and/or data supplied by the VCB be provided on an annual basis and to be *acknowledged by using the following statement*:

"The Victorian Cancer Biobank through the Cancer Council Victoria as Lead Agency is supported by the Victorian Government through the Victorian Cancer Agency- a business unit of the Department of Health and Human Services"

3. Application Process

3.1. The VCB Executive Officer in consultation with the Access Committee reviews applications for biospecimens and/or services to:

a) Match the capabilities of the VCB in terms of feasibility, prioritisation and/or the quantities of tissue being requested.

b) Evidence that the project has undergone a scientific or peer-review process and has been approved by a registered NHMRC (or equivalent) Human Research Ethics Committee (HREC).

c) Approve or reject applications based on the above considerations.

d) Resolve issues of competing demands.

3.2. Applications are approved/not approved within 5 business days of submission

3.3. Upon approval, you will be asked to complete a Materials Transfer Agreement **(MTA)** or a Master Services Agreement **(MSA)**. **Note:** The provision of biospecimens or services cannot commence until the fully executed MTA or MSA has been returned.

a) MTAs or MSAs that have not been returned within 90 days will not be followed up i.e., no further action will be taken by the VCB to determine the status of the application.

b) Applicants who have not returned the MTA's or MSA within 90 days may be asked to re-apply and be subject to another application processing fee.

3.4. Amendments to original projects may be made by submitting an Amendment to Change Request (Form C). There is an amendment processing fee involved and amendments can only be accepted if they fall within the scope of your HREC approved application.

4. VCB Letter of Support

4.1 VCB can issue a Letter of Support to principal investigator's planning to use VCB bio-materials/services for their research project.

4.2 The Letter of Support is issued after consultation with the PI, to assist in appropriate budgeting for projects requiring biospecimens and/or services.

a) To discuss a VCB Letter of Support please contact the VCB Applications Manager: VCBEnquiries@cancervic.org.au

5 Fees

5.1 The Victorian Cancer Biobank collects cost recovery fees to offset the substantial costs of collecting, processing, storing and annotating biospecimens.

5.2 Cost recovery rates were reviewed annually and are benchmarked against local and international biobanks, such as the NUHS Tissue Biorepository and Stanford Cancer Institute Tissue Bank.

5.3 Fees are reviewed annually and may change without notice. The VCB's Cost Recovery Fee Schedule is available by contacting the VCB Applications Manager.

6 Ethics Approval

6.1 The principal investigator must have obtained approval from a registered NHMRC (or equivalent) Human Research Ethics Committee (HREC) before materials and/or data may be released.

6.2 Projects exempt from review will be considered. Please provide your ethics committee (or equivalent) letter of exemption with your application.

6.3 Projects involving genetic testing/profiling or analysis are only accepted with full HREC approval (i.e. non expedited review).

7 Data

7.1 Data is provided in de-identified (coded) format.

7.2 The VCB maintains the re-identifying link between participants and their data.

7.3 Snapshot of data available:

a) Category 1 Data: age, sex clinical diagnosis, tissue pathology, grade/stage, diagnostic biomarker and mutation status (where available)

b) Category 2 Data: Category 1 data plus pre-surgical and/or post-adjuvant therapies, smoking status and medications.

c) Category 3 Data: Category 1 & 2 plus personal history of cancer, survival data and treatment response. .

8 Biospecimens

8.1 **Tumour content** of fixed and frozen tissue samples are assessed by pathology verification (H&E) of the associated fixed or OCT embedded tissue fragment. Whilst we aim to provide a minimum of 50% tumour content, the tumour content may vary for some tissue types.

8.2 **Blood** (Plasma, Serum, Buffy Coats and PBMNCs) are collected as closely as possible to the time of surgery and processed within 2 hours of collection.

8.3 **Follow-up bloods** are collected based on project specific time points.

8.4 **DNA and RNA** can be extracted from tissue or blood.

8.5 **Normal control tissue**. Surgical patients with benign conditions or who are having cosmetic or prophylactic procedures are asked to donate blood and tissue.

8.6 **Healthy donors**, such as family members and friends accompanying patients, as well as visitors to our host institutions may be asked to donate blood samples as controls.

8.7 **Fresh tissue.** Access to fresh tissue samples is more restrictive than requests for Formalin-Fixed Paraffin Embedded (FFPE) because they cannot be recalled for diagnostic assessment if the main specimen submitted to Pathology is judged insufficient. Therefore please note the following:

*a) While some participants may give pre-operative verbal consent to enable the collection of fresh tissue, a signed, post-operative **consent must be obtained by Biobank staff within 90 days of a procedure**. If the post-operative consent cannot be obtained, cell lines and xenografts etc., constructed from the harvested fresh tissue **MUST** be destroyed and no information retained.*

b) Fresh tissue collections incur a special pathology tissue cut-up fee. The pathologist will try and select appropriate tissue based on the investigators specification. However, without microscopic review the pathologist cannot guarantee that all areas of interest will be present in the fresh tissue. While the

VCB will not charge for the fresh tissue fragment, the researcher will be charged the pathology tissue cut-up fee and any applicable courier fees. Please contact the Applications Manager for more information.

9 Condition of Use

9.1 Biospecimens and data supplied by the Victorian Cancer Biobank may be used only for the scientific/medical purposes as stated in the Victorian Cancer Biobank Material Transfer Agreement.

9.2 Researchers must not attempt to identify any VCB donor unless they have specific ethics approval to access identified information and the participant has consented to be identified.

10 Disclaimers

10.1 Biospecimens for the VCB are selected with great care by pathologists; however, the VCB, its sponsors and contributors accept no responsibility for the inadvertent provision of incorrect materials or data.

10.2 The VCB does not knowingly collect or distribute infectious material, e.g. HIV, TB, Hepatitis B or Hepatitis C. Screening for these infectious agents is not routinely performed, therefore all biospecimens should be treated as bio-hazardous material. If, in the event infectious material is detected applicants need to be aware that full cooperation from the donor may not occur. The VCB and its host institution will endeavour to obtained relevant clinical data within the ethical boundaries but the onus is on the applicant to pursue donor infectious disease testing, including consenting the donor.

10.3 The applicant assumes all risk and responsibility for the handling, storage and use of samples provided by the VCB and for informing and training all personnel in the dangers, hazards and procedures for the safe handling of human biospecimens.

11 Payment

11.1 Payment for VCB Biospecimens and/or Services is due 30 days from the end of month.

11.2 Payments not received within 60 days may result in the temporary suspension of service until payment is received.