ADTB How to Apply and Conditions of Use

Australian Donation and Transplantation BIOBANK

Instructions

Please read the ADTB How to Apply and Conditions of Use and sign at the end of the document to indicate your acceptance of the terms. Please direct any issues or queries to us prior to signature by contacting adtb@austin.org.au.

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Australian Donation and Transplantation BIOBANK

1. How To Apply

1.1 The Australian Donation and Transplant Biobank (ADTB) is an investigator-led open-access platform that is available to all researchers who have Human Research Ethics Committee (or equivalent) approval for their research project.

1.2 Researchers who wish to access donor organs/samples through the ADTB must submit the following documents for review:

1. ADTB Sample Access Form for research project
2. Ethics approval letter for research project
3. Approved human research ethics application for project
4. Amendment requests and approvals, if applicable
5. Researcher's CV
6. Current research protocol listed on approval letter
7. Material Transfer Agreement

1.3 Application documents can be submitted to adtb@austin.org.au.

1.4 Researchers are encouraged to notify the ADTB of their intention to apply prior to submitting documents to discuss availability of data and biospecimens.

1.5 Researchers must submit a separate application for each individual research project. The named Principal Investigator is ultimately responsible for the application and adherence to the Conditions of Use.

2. Ethics Approval

2.1 The Principal Investigator (PI) of the research project must obtain approval from a registered NHMRC (or equivalent) Human Research Ethics Committee (HREC) before the ADTB will issue approval for sample access.

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

2.3 Primary consent for donation to the ADTB is obtained by DonateLife Donation Specialist Nursing Coordinators (DSNCs) following consent for deceased organ and tissue donation for transplantation. The DSNC provides the donor's Senior Available Next of Kin (SANOK) with written information about the ADTB as outlined in the general ADTB Information Sheet and Consent Form and refers them to the ADTB website (www.adtbiobank.org) where information is provided about the research projects which use ADTB donations.

2.4 The primary ADTB consent does not include consent for the use of samples in research which is considered ethically complex. Research considered ethically complex includes genetic testing, the creation of cell lines and use of donated samples in animal models. Research which is considered ethically complex is still possible, however secondary consent and more comprehensive project approval process is required:

1. Researchers must clearly indicate whether their project involves research considered ethically complex in their Sample Access Form and ethics submission.

2. Projects that involve ethically complex research require non-expedited HREC review

3. Projects that involve ethically complex research require Lifeblood Ethics Committee approval which may take up to 2 months.

4. Secondary consent for ethically complex research must be obtained from the SANOK by the researcher. ADTB will not seek secondary consent on behalf of the researcher.

At the time of primary ADTB consent, the SANOK will be asked if they are willing to be contacted about future opportunities for donated samples to be used in ethically complex research projects. When this consent is provided, the ADTB will provide the SANOK's personal contact details to the researcher for the purpose of secondary consent (if applicable). Contact may only occur at least three months after the original donation, to avoid causing potential distress to families in the immediate period after the death of their loved one. The researcher or their delegate will then seek specific secondary consent for the use of relevant samples at that time, after written and verbal information is provided about the risks and potential benefits associated with the specific approved research project. The plain language statements and consent process used in these circumstances will be part of the HREC-approved study protocol presented to the ADTB when samples are requested by researchers.

2.5 Researchers are required to report any medically actionable results resulting from their research to ADTB due to the potential health implications for donor families (per NHMRC National Statement on Ethical Conduct in Human Research (2007) - Updated 2018, sections 3.3.36-3.3.61). If applicable, researchers must address the issue of findings with potential clinical significance in their original ethics application. Applications with the potential for findings of clinical significance for donor families require Lifeblood Ethics Committee approval which may take up to 2 months.

2.6 Organ donor infections and cancers can be transmitted to the transplant recipient with the transplanted organ. Researchers are required to report any medical results resulting from their research that may have implications for the recipients of organs from a donor to the ADTB. Examples include infections and cancers that were not known about at the time of the donation operation.

3. Review by the Sample Access Committee and Lifeblood

3.1 The ADTB Sample Access Committee (SAC) reviews applications to:

a) Ensure the capabilities of the ADTB match those of the project in terms of feasibility, prioritisation and/or the quantities of tissue being requested

b) Review 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) Ensure the scope and methods of the project under review fall within with the ethics approval granted to the ADTB

d) Resolve issues of competing demand with other researchers

3.2 The SAC will endeavour to assess all applications within 10 business days of submission.

3.3 The SAC may issue queries which are required to be answered satisfactorily prior to final approval.

3.4 After SAC approval, the application will be provided to the Lifeblood Ethics Committee for reciprocal ethical approval which may take up to 20 business days.

3.5 Upon approval or while awaiting approval, a Materials Transfer Agreement (MTA) must be drafted and agreed upon by both host institutions. The provision of biospecimens or services cannot commence until the fully executed MTA has been returned. MTAs that have not been returned within 120 days may not be followed up i.e., no further action will be taken by the ADTB to determine the status of the application.

4. ADTB Letter of Support

4.1 A Letter of Support may be provided upon request to researchers who plan to utilise ADTB samples for their research project.

4.2 The Letter of Support is intended to assist with ethics and/or funding applications.

5. Fees

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

5.2 Fees are reviewed annually. Thirty days notice will be given prior to any change in fees. The ADTB Cost Recovery Fee Schedule will be made available upon request by contacting adtb@austin.org.au.

6. Post-Approval Requirements

6.1 Approved researchers are required to provide an annual progress report to the ADTB, detailing the status of their project, changes to funding, resultant patents/commercialisation and a list of abstracts, publications and presentations resulting from materials and/or data supplied by the ADTB. A copy of the annual HREC progress report should be attached.

6.2 Approved researchers are required to notify the ADTB of any ethics amendments and provide copies of amendment requests and approval letters, If amended projects deviate substantially from the initial application, the Sample Access Committee may be required to review the amendment before samples can be provided for the project amendment.

6.3 Changes to ADTB service provision which do not require ethics amendment will be considered following submission of an Amendment Request Form. Amendments can only be accepted if they fall within the scope of your HREC approval and continue to be consistent with the ADTB Conditions of Use.

6.4 Donor families are interested in the research their loved one's donated samples have supported. Researchers are asked to provide a short testimonial about the benefits of using ADTB samples for their research for publication on the ADTB website (adtbiobank.org).

6.5 The ADTB is an investigator-led project. The ADTB requests that ADTB staff be offered co-authorship in any publication or presentations of the research at any scientific meetings. Consideration for authorship for ADTB investigators and team should be according to ICMJE recommendation.

http://www.icmje.org/recommendations/browse/roles-and-responsibilities/defining-the-role-ofauthors-and-contributors.html

6.6 The organ donor families should be acknowledged by using the following statement: "We gratefully acknowledge the generosity of the organ donor families in providing valuable tissue samples."

6.7 Requests for extension of MTAs can be made by emailing adtb@austin.org.au. We suggest allowing 3 months for the MTA extension to be executed by both parties.

7. Data

7.1 Data is provided in de-identified (coded) format. The ADTB maintains the re-identifying link between organ donors and their data.

7.2 Researchers should indicate which clinical data they require in both the ADTB Sample Access Form and the project protocol.

7.3 Category 1 Data will be provided to researchers before the donation surgery to assist in their decision to accept samples. Routine or pre-approved Category 2 Data will be provided to researchers within a week of the donation surgery or within 2 weeks of an additional request. In some cases and with prior approval, Category 2 Data may be provided before the donation surgery. The variables included in each category are outlined below:

a) Category 1 Data: Age, sex, type of donation (circulatory or brain death), active HBV/HCV/HIV infection

b) Category 2 Data: Cause of death, co-morbidities, smoking status, HLA typing, medications, microbiological results, details of donation operation (e.g. warm ischemia time), screening serology

8. Biospecimens

8.1 The ADTB's office hours are Monday to Friday, 8am to 5pm, however notification of available donor samples is often made by the ADTB Retrieval Surgeon on the night prior to donation surgery. Researchers must submit all requests for tissue at or before 8am on the day of surgery.

8.2 Researchers may request special consideration for weekend access if rare tissues are required. Additional courier fees may apply.

8.3 Blood and fresh tissue will be transported on ice to the researcher by a third-party courier service or the ADTB Retrieval Surgeon. The time from sample retrieval in theatre to sample distribution is an interval of approximately 1 to 6 hours (depending on the location of the

donation operation which may be at any hospital in Victoria, Tasmania or NSW border). Samples are usually delivered in the late afternoon or evening.

8.4 Tissue samples will typically be suspended in perfusion fluid (Soltran®) during the donation operation and taken to Austin Health on ice. Samples will then be re-suspended into complete RPMI (RPMI, 5% FBS, streptomycin and gentamicin and L-glutamate) and shipped on ice. Alternative collection requirements may be accommodated: please include these details in the Sample Access Form.

8.5 ADTB stores samples for use in future research. Tissues will be frozen or Formalin-Fixed Paraffin Embedded (FFPE) within 6 hours of collection. Alternative collection requirements may be accommodated: please include these details in the Sample Access Form.

9. Disclaimers

9.1 Biospecimens and data supplied by the ADTB may only be used for research purposes as stated in the ADTB Material Transfer Agreement.

9.2 Researchers must not attempt to identify any ADTB donor.

9.3 Biospecimens for the ADTB are selected with great care by surgeons; however, the ADTB accepts no responsibility for the inadvertent provision of incorrect materials or data.

9.4 The ADTB receives information on HIV, Hepatitis B and Hepatitis C status from DonateLife Victoria and will notify researchers if the donor has active HIV, Hepatitis B or Hepatis C infection (e.g., nucleic acid test is positive). However, screening for infectious agents is not complete and all biospecimens should be treated as potentially biohazardous material. It is the researcher's responsibility to only accept ADTB samples if they have the appropriate biohazard safety policies, procedures and institutional approvals in place.

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

9.6 The ADTB manages sample requests from a large number of researchers. If demand for samples exceeds sample provision, no further samples will be provided to researchers who have already received the allocated number of samples initially requested, unless supply of samples improves.

9.7 The ADTB How to Apply and Conditions of Use document may be updated from time to time. Researchers will be asked to sign updated versions.

10. Payment

10.1 Invoicing for ATDB services will be sent on a quarterly basis.

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

11. Principal Investigator Declaration

Principal Investigator Declaration	
I have read and understood and agree with the conditions for use as detailed in this document.	
Principal Investigator's Name	Signature and Date