NSW Organ and Tissue Donation Service

RESEARCH APPLICATION FORM

APPLICATION FOR WORK INVOLVING ACCESS TO AND/OR USE OF BIOLOGICAL MATERIAL AND/OR DATA BY RESEARCHERS

IMPORTANT:

Please read the NSW Organ and Tissue Donation Research Protocol and *Conditions of Use* on page 5 prior to completing this application form.

FOR FURTHER INFORMATION PLEASE CONTACT:

Manager

NSW Tissue Banks

GPO Box 1614

Sydney NSW 2001

Tel: 02 9382 7855

Fax: 02 9382 7845

ALL SECTIONS MUST BE COMPLETED PRIOR TO SUBMISSION TO:

The NSW OTDS Research Steering Committee

C/- NSW Tissue Banks

GPO Box 1614

Sydney NSW 2001

PRINCIPAL INVESTIGATOR		
Name:	Affiliation:	
Address:		
Suburb	State	Postcode
Phone:	Email:	

CO INVESTIGATOR (S)	
Name:	Affiliation:
Name:	Affiliation:

TITLE OF PROJECT

Please state the duration of the project e.g. 2009-2012: _____

Proposed commencement date: _____

Proposed amount of tissue required: _____

Type of tissue required (please be as specific as possible): _____

Has the Principal or Co-Investigator/s previously applied to the NSW OTDS for other projects?

YES ☐ NO ☐

BRIEF SUMMARY OF STUDY

SECTION 1 Project Explanation

On pages separate to this document, please provide details about the project:

a) Background and introduction

b) Hypotheses and aims

c) Research plan (including methods to be used)

d) Access or tissue required (type, scope and criteria, clinical/pathological staging required, number of specimens etc)

e) Preliminary results

f) Significance of the research

g) Relevant publications

Please address all of the criteria, make responses as clear and succinct as possible and provide this information in 4 pages or less and attach to this application form for submission.

SECTION 2 Ethics Committee Approval

It is important that your work accords with the ethical and regulatory standards that govern the NSW Organ and Tissue Donation Service (OTDS). Please provide evidence of ethical clearance for the project including copies of approved institutional human research ethics applications and all correspondence with the human research ethics committee. Where applicable this must be provided from each of the participating institutions.

DOES THE PROJECT HAVE ETHICS APPROVAL? YES ☐ NO ☐
(if yes, please provide evidence)

IF NOT, IS AN HREC APPLICATION IN PROGRESS? YES ☐ NO ☐

COMMENTS:

SECTION 3 Scientific Review and Funding

To assist the committee in assessing the merit of the research proposed, it is useful know if the work has been scientifically reviewed and has successfully obtained grant funding. If so, please provide evidence of peer-reviewed success of the proposed research and wherever possible, provide copies of the referees' reports.

HAS THE PROJECT BEEN SCIENTIFICALLY REVIEWED? YES ☐ NO ☐

IF YES, BY A GRANTING BODY? YES ☐ NO ☐
(if yes, please provide evidence)

SPECIFY GRANTING BODY _____

REVIEWED BY OTHER PARTY? Please Specify _____

DO YOU HAVE FUNDING FOR THIS STUDY? YES ☐ NO ☐
(if yes, please provide evidence)

IF NOT, IS FUNDING BEING SOUGHT? YES ☐ NO ☐

SECTION 4 Tissue Transport

If tissue specimens are being requested, please complete the following:

Contact Name, Role and contact number	
Delivery address	
Mode of transport required	
Suggested arrangement for payment of transport	

NSW Organ and Tissue Donation Service

CONDITIONS OF USE FOR ACCESS TO AND/OR USE OF BIOLOGICAL MATERIAL AND/OR DATA

Conditions of Use

Tissue specimens and/or data from the NSW OTDS is provided with the intention of facilitating research into conditions specific to the tissue or related fields. The specimens and/or the data can only be used in the manner described in the application as provided to the NSW OTDS Research Steering Committee and must be either discarded via the routine clinical waste procedures or returned after use. Any change in the project direction must be communicated in writing to the NSW OTDS Research Steering Committee who deserves the right to withdraw support.

Tissue Specimens

Tissue specimens from the NSW OTDS are provided without revealing the donors name or date of birth. No attempts can be made by the Investigator to identify or contact the donor or their next of kin. If additional clinical information is required it should be requested through the contact person for the NSW OTDS Research Steering Committee.

Specimens are provided in compliance with the 1983 NSW Human Tissue Act, NH&MRC Organ and Tissue Donation after Death, for Transplantation and the NSW Ministry of Health Policy Directives PD2013_001[1]and PD2013_002[2] and Guideline GL2006_021[3].

Specimen Safety

Although all tissue retrieved with the intention of transplantation is screened for Hep C, Hep B and HIV, all specimens should be handled with the utmost of care to prevent infection from pathogens. No responsibility will be taken for injury or illness that may occur to investigators handling the specimens.

Commercialising and Intellectual Property

Specimens and/or data cannot be given or sold to other investigators or used for commercial products or purpose. The investigator has full intellectual property over any discoveries derived from the specimens and/or data but findings that may have an impact on the transplant recipients of related tissue must be notified back to the NSW OTDS Research Steering Committee immediately.

Sample Preparation Cost

NSW law prohibits trade in human tissues. Tissue may be provided to the investigator at no charge but in most cases considerable work and expense is involved in the retrieval and preparation of the tissue for dispatch and some cost recovery will be necessary. Any cost recovery fees will be discussed with the investigator beforehand.

Courier Costs

The cost of shipping the specimens will be borne by the investigator/institution requesting the specimens and not by the NSW Organ and Tissue Donation Service.

---

[1] PD2013_001 Deceased Organ and Tissue Donation – Consent and Other Procedural Requirements.
[2] PD20013_002 Designated Officer Policy and Procedures
[3] GL2006_021 Human Tissue – Requirements of the Human Tissue Act 1983 in relation to research and use of tissue.

Sydney Based Investigators
For investigators based in the Sydney region it is possible for specimens to be collected directly from the NSW Tissue Banks if they are the supplier of the tissue.

Application Requirements
Scientific Review
The investigator/s are required to show evidence that the proposed project has been reviewed scientifically by independent means. This could include a successful grant application, peer-reviewed publication related to the project in which the investigator is a co-author, a letter from an internal review board or scientific advisory committee or from an independent scientist not related to the project and not within the same program/department as the investigator. Approval from the investigators institutes' human ethics committee does not represent an independent scientific review of the proposed project using NSW OTDS specimens.

Ethics Approval
The investigators are required to obtain ethics approval from an appropriate Public Health Organisation Human Research and Ethics Committee (HREC) as part of this submission. Should the ethics committee require a letter of support from the NSW OTDS, this is to be clearly indicated on the application form. All applications without intention to achieve ethics approval will be rejected.

Application Assessment
Applications will be assessed on an individual basis by the NSW OTDS Research Steering Committee. The committee is comprised of representatives of the State and Tissue Bank Medical Directors; NSW OTDS Management; Operational and Laboratory representatives; a SESLHD Research Support Office representative and an independent member. Consultation can be made to external experts as required.

All applications will be assessed against the following criteria:
- Justified and efficient use of the tissue and/or data;
- Suitably credentialed investigator;
- Impact on the quality system and regulatory framework within which the NSW OTDS operates;
- Availability of the required tissue specimens and/or data.

Following assessment of each application, the investigator will be informed if their application is successful. If the NSW OTDS Research Steering Committee identifies any questions in regards to an application, the investigator will be asked to respond to the committees questions in writing.

When the project is deemed successful the investigator will be required to confirm HREC approval and submit a South Eastern Sydney Local Health District (SESLHD) Site Specific Assessment (SSA) to the SESLHD Research Governance Officer on the link below, before execution of the Material Transfer Agreement (MTA) and supply of the required tissue and/or data.
http://www.seslhd.health.nsw.gov.au/POWH/researchsupport/Governance/default.asp

Progress Reports and Publications

The investigator/s are required to provide a report 12 months from receiving the first tissue specimen and/or data and every 12 months after that and on completion of the project. These reports should indicate the percentage of specimens that have provided useful information, whether the study is still continuing and the anticipated date of study completion. The results of the study will not be requested. At study completion, any remaining tissue specimens should be returned to the NSW OTDS or discarded via routine clinical waste procedures.

A copy of all publications (peer-reviewed manuscripts and conference abstracts) resulting from use of NSW OTDS tissue specimens and/or data should be forwarded to the NSW OTDS Research Steering Committee upon acceptance by the conference/journal committee.

Acknowledgement and Collaborations

The investigator/s are required to acknowledge the NSW OTDS as the source of the tissue specimens and/or data in all publications or presentations resulting from research undertaken with NSW OTDS tissue specimens and/or data. Failure to recognise the NSW OTDS in this manner will render the individual and/or the institution ineligible for future applications.

SECTION 5 Agreement Statement and Signatures

By signing this document, I …… (*Principal Investigator*) confirm that the information provided in this application is accurate and that I have read the *Conditions of Use* and agree to abide by all of the conditions.

Signature of Principal Investigator: _____

Full Name (printed): _____

Date: _____

Signature of Co-Investigator: _____

Full Name (printed): _____

Date: _____

Signature of Co-Investigator: _____

Full Name (printed): _____

Date: _____