



Health
NSW Organ & Tissue
Donation Service

Incorporating:
NSW Bone Bank
Lions NSW Eye Bank
Australian Ocular Biobank

Part of the
DonateLife
network



NSW Organ and Tissue Donation Service

RESEARCH PROTOCOL

**FOR ACCESS TO AND/OR USE OF BIOLOGICAL MATERIAL AND/OR DATA BY
RESEARCHERS**

BACKGROUND

The NSW Organ and Tissue Donation Service (OTDS) is a public health organisation hosted by South Eastern Sydney Local Health District (SESLHD). The NSW OTDS and its Network provides a state-wide clinical service for the identification and coordination of organ and/or tissue donors; retrieval; and allocation of organs and tissues for transplantation.

Deceased donor identification, assessment and authorisation is undertaken in accordance with a regulatory framework that includes the:

- 1983 NSW Human Tissue Actⁱ;
- 2009 NSW Coroners Actⁱⁱ ;
- NH&MRC Guideline Organ and Tissue Donation after Death, for Transplantationⁱⁱⁱ;
- NSW Ministry of Health Policy Directive PD2013_01^{iv}.

Authorisation for the retrieval of organs and/or tissue from a deceased donor for transplantation to the body of a living person and/or research is undertaken in accordance with PD2013_01 and documented on SMR020.030 *Consent and Authority for removal of tissue after death*^v

The ethical responsibility the NSW OTDS has to the donors and the tissue retrieved, is one of stewardship^{vi}.

The NSW OTDS Research Steering Committee is made up 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.

The NSW OTDS Research Steering Committee meets biannually but can review applications off line as needed.

DEFINITIONS & ABBREVIATIONS

Australian Ocular Biobank – biobank of ocular tissue and associated data from living and deceased donors, governed by the NSW Tissue Banks.

DTA- Data Transfer Agreement

HREC - Human Research Ethics Committee

LNR - Low Negligible Risk

MTA - Material Transfer Agreement.

PHO - Public Health Organisation

SSA - Site Specific Assessment

PROCEDURE

Applications for research must use the appropriate application form or provide the required information in a similar format to be considered. All applications will be assessed against the criteria listed in Appendix 1.

When a project involves human tissue, the researcher will be required to confirm HREC approval with a PHO HREC and submit it along with a Site Specific Assessment (SSA) to

the SESLHD Research Governance Officer via the link given below before execution of the Material Transfer Agreement (MTA) and supply of the required tissue.

When a project involves data only, the researcher will be required to confirm HREC approval with a PHO HREC and submit it to the SESLHD Research Governance Officer via the link given below before execution of the Data Transfer Agreement (DTA) and supply of the required data.

SESLHD Research Support office Contact:

Phone (02) 9382 3587,

Fax (02) 9382 2813.

Website: <https://www.seslhd.health.nsw.gov.au/services-clinics/directory/seslhd-research-for-researchers/research-support-office-contact>

Email: SESLHD-RSO@health.nsw.gov.au

The NSW OTDS Research Steering Committee recommends that all prospective researchers contact the NSW OTDS early in the application phase, particularly if a letter of support is required for the ethics application.

Application and Review Process

1. Researcher identifies specimens/data or type of access required
2. Contact is made with the NSW OTDS Research Steering Committee or NSW OTDS Agency Kogarah office (02 8566 1700) or the NSW Tissue Banks (02 9382 7855).
3. Application is completed and sent to the NSW OTDS Research Steering Committee. Of note, this may be undertaken prior to ethics approval is confirmed to facilitate a letter of support.
4. Application is reviewed by appropriate members of the NSW OTDS Research Steering Committee and external experts as required.
5. Communication back to researchers:
 - a. Application pre-HREC approval
 - i. Application accepted and letter of in-principle support provided.
 - ii. Application deferred with or without option to resubmit.
 - b. Application post-HREC approval
 - i. Application accepted.
 - ii. Application deferred with or without option to resubmit.
6. Application involves human tissue:
 - a. Researcher provides the confirmed HREC Ethics approval and completed SSA to the SESLHD Research Support Office with communication of same to the NSW OTDS Research Steering Committee.
7. Application does not involve human tissue:
 - a. Researcher provides the confirmed HREC Ethics approval to the SESLHD Research Support Office with communication of same to the NSW OTDS Research Steering Committee.
8. Application reviewed by the SESLHD Research Support Office and the MTA provided to the researcher to be signed and returned.

9. Executed MTA confirmed with the researcher and NSW OTDS Research Steering Committee.

Post Review Process

1. Communication between the researcher and the NSW OTDS Research Steering Committee or relevant officers from the NSW OTDS to confirm access and provision of requested tissue and/or data.
2. Researchers responsibility:
 - a. To abide by the MTA;
 - b. Provide an annual report to the NSW OTDS Research Steering Committee that may include:
 - i. Confirmation of the numbers/amount of tissue and/or data received to date;
 - ii. Confirmation that all tissue received has been respectfully disposed of after it's intended use;
 - iii. Confirmation that the data received has only been used for the purpose intended in the research application;
 - c. Ensure that the NSW OTDS is acknowledged as the source of the tissue/data in all publications and presentations;
 - d. Provide copies or links to publications resulting from the research; and
 - e. To monitor status of the ethics approval.
3. Communication as required with relevant NSW OTDS Network staff members regarding any implications for Family Donation Conversations; allocation and transportation of tissue; access to donor information or other data elements.

APPENDIX 1. Application Review Criteria

Criteria	Yes	No	Comments (initial and date comment)
Suitably credentialed investigator			
Justified and efficient use of the tissue and/or data			
Availability of the required tissue specimens and/or data			
Impact on operational activities, quality system and regulatory framework (if applicable):			
• Protocols and Procedures:			
• Legislative: Human Tissue Act and Coroners Act:			
• Logistical (including staff time):			
• Work Place Health & Safety:			
• Financial implications:			
• Other.....			
Recommendation:			

ⁱ NSW Human Tissue Act 1983 http://www.austlii.edu.au/au/legis/nsw/consol_act/hta1983160/

ⁱⁱ NSW Coroners Act 2009 http://www.austlii.edu.au/au/legis/nsw/consol_act/ca2009120/

ⁱⁱⁱ NH&MRC Guideline Organ and Tissue Donation after Death, for Transplantation
http://www.nhmrc.gov.au/_files_nhmrc/publications/attachments/e75.pdf

^{iv} PD2013_001 Deceased Organ and Tissue Donation – Consent and Other Procedural Requirements. http://www0.health.nsw.gov.au/policies/pd/2013/PD2013_001.html

^v NSW Health Form SMR020.30 Consent and Authority for removal of tissue after death

^{vi} NHMRC Ethics and the exchange and commercialisation of products derived from human tissue. October 2011.

https://www.nhmrc.gov.au/_files_nhmrc/publications/attachments/e103_ecpd_humantissue_111019.pdf