St Vincent's Hospital

St Vincent's Hospital Sydney Limited

Policy for the Collection, Use, Supply and Transfer of Material (including Human Tissue) for Medical Research

1 Purpose and Scope

1.1 This document describes the policy of St Vincent's Hospital Sydney Limited (the **Hospital**) regarding:

1.1.1 the collection, use, supply and transfer of explanted Material which has been explanted at the Hospital; and

1.1.2 the conduct of research at the Hospital involving Material.

1.2 The policy aims to provide a consistent framework for the Hospital to ensure the collection, use, supply and transfer of Material complies with legal, ethical, medical and applicable government standards.

2 Policy Statement

2.1 The Hospital recognizes the contribution that is made by those who donate Material for medical research.

2.2 The Hospital will meet its legislative and ethical obligations and value the contribution made by those who donate their Material for medical research.

2.3 Medical research involving Material must observe the fundamental ethical principle of respect of the donor, including the provision of full information, consent, professional removal of samples and secure storage of the Material and to maintain confidentiality and privacy.

2.4 The cultural or religious sensitivities of the donor should be considered when soliciting or accepting Material.

2.5 The collection, use, supply and transfer of Material for research and research conducted at the Hospital must also comply with the Catholic Code of Ethics. This includes in relation to stem cells.

2.6 The collection, use, supply and transfer of Material by the Hospital must be carried out with approval of the Hospital HREC and the Designated Officer, through formal application in accordance with this Policy.

3 Procedure

3.1 Application form to use human tissue for medical research

3.1.1 A decision as to donation must be made in accordance with the relevant NSW Health policies (noted below).

3.1.2 An organization seeking Material from the Hospital must enter into a Material Transfer Agreement with the Hospital in the form of **Annexure B**. Any amendment to the standard form must be approved by the Executive Director or the Director of Clinical Services.

3.2 Upon each application for Material, the applicant is required to complete a Material Request Form (**Annexure A**) and follow the directions for submissions. The Material Request Form must be sent to the Director of Clinical Services.

3.3 Each application to the HREC should contain (as relevant) the following;

3.3.1 A description of the tissue requested.

3.3.2 A description of the proposed research, including Research Protocol.

3.3.3 A description of the Principal Investigator and relevant research parties, including Sponsor (if applicable).

3.3.4 Consent Form.

3.3.5 Information provided to research subjects.

3.3.6 Storage arrangements.

3.3.7 Retention period.

3.3.8 Arrangements for the eventual dispose of the tissue.

3.3.9 The review and approval of applications to utilise Material when consent has been given by the Patient and/or Next of Kin, is delegated to the Designated Officer.

3.3.10 The Designated Officer will assess the application to ensure compliance with the HREC guidelines and if the HREC criteria are met, submit the application for HREC approval.

3.3.11 If HREC approval is granted, then the Designated Officer has the *discretion* to approve the transfer. No reasons are required to be given, there is no right of appeal from this decision.

3.3.12 The Designated Officer must not grant approval without HREC approval.

3.3.13 Approval is usually granted for no longer than 12 months.

3.3.14 Researchers/recipients of the Material are required to submit a progress report to the Designated Officer on the completion of the research and upon each anniversary of approval.

3.3.15 Researchers can apply for an extension of approval if required.

3.3.16 The Designated Officer will report to the HREC every [12 months].

3.3.17 Note that special provision/restrictions apply to coronial cases (refer to NSW Health Policies below).

4 Ethics

4.1 The collection and use of Material for scientific research at the Hospital must be conducted in accordance with all relevant laws and policies including:

4.1.1 The National Statement on Ethical Conduct in Human Research, in particular Chapter 3.4.

4.1.2 Organ and Tissue Donation by Living Donors - Guidelines for Ethical Practice for Health Professionals (NHMRC).

4.1.3 Making a decision about Organ and Tissue Donation After Death (NHMRC).

4.1.4 Organ and tissue donation in Australia from deceased donors is based on the following ethical principles:

(a) Organs and tissues are only removed once the person is dead.

(b) Donation is intended to benefit others. No reward or even acknowledgement by those who benefit is expected.

(c) A person's wishes about donation are respected.

(d) Families are given time to consider and discuss their views. If a close family member objects, donation will not go ahead.

(e) Families are supported and cared for throughout the donation process. Counselling may be provided at the time of donation or later if the family wishes.

(f) The person donating is always treated with respect and dignity.

(g) Organs and tissues are allocated fairly, following specific processes for each type of organ or tissue as well as criteria for matching the donation to the recipient.[1]

4.1.5 Consent to use tissue samples or organs for research requires the project to have obtained ethical approval by an HREC.

4.2 In the case of Aboriginal and Torres Strait Islander families, an Aboriginal Liaison Officer or Aboriginal Health Care worker should be available to assist with the consent process.

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[1] Making a Decision About Organ and Tissue Donation After Death 2007 (NRMHC)

5 Consent

Tissue blocks and tissue slides

5.1 The law allows tissue held in a tissue block or tissue slide to be used for research. It is best practice to still obtain consent from the donor.

Live donors of tissue explanted for medical treatment

5.2 Where tissue is removed from a live person, the common law requires the person's consent to the removal, otherwise the removal would be a battery.

5.3 Live donors may consent to the donation of Material which is explanted in the ordinary course of medical treatment (ie explanted for therapeutic purposes and not explanted specifically for research purposes).

5.4 Written consent is required to use that tissue for research either before or after removal.

Live donors of tissue explanted for research

5.5 Where tissue is removed from a live person, the common law requires the person's consent to the removal, otherwise the removal would be a battery.

5.6 Consent from live donors (other than a child) for the removal of specified *regenerative tissue* for scientific purposes must be obtained in accordance with the NSW Health Policy Directive on Consent to Medical Treatment - Patient information and the Human Tissue Act.

5.7 A medical officer not involved in the removal of the tissue should issue a certificate stating that written consent was given in the presence of the officer and must comply with all of the following requirements:

5.7.1 That before consent was given, the nature and effect of the tissue removal had been explained. If tissue is to be removed from a child then the officer must state that this has been explained to the parents of the child.

5.7.2 That the options for the use of tissue removed during the procedure had been explained and consented to by the patient/next of kin/child (if appropriate).

5.7.3 The officer is satisfied that the patient or the parent/guardian and child were of sound mind and the consent was freely given.

5.7.4 That the patient or parent/guardian has not subsequently revoked the written consent.

5.7.5 If the tissue is to be removed from a living child that the child remains in agreement with the proposed tissue removal and transplantation.

5.8 In all cases, removal of tissue from living persons cannot take place until 24 hours after the written consent was given.[2]

5.9 Non-regenerative tissue may only be removed from the body of an adult person for transplantation purposes (ie not for research) - apart from removal in the course of treatment carried out for the benefit of the adult.

5.10 Non-regenerative tissue may not be removed from the body of a living child unless removed during the course or treatment carried out for the benefit of the child.[3]

5.11 In no circumstances is tissue to be removed from the body of a deceased child who is or was a ward of the State for research purposes, either with or without the consent from any person.[4]

Removal of tissue after death

5.12 For the purposes of NSW Law (Human Tissue Act), a person has died when there has occurred:

5.12.1 irreversible cessation of all function of the person's brain; or

5.12.2 Irreversible cessation of circulation of blood in the person's body.

5.13 An authority under the Human Tissue Act does not extend to tissue taken during medical, dental or surgical treatment whilst the person was alive or for the purposes of a post mortem examination.

5.14 Section 23 of the Human Tissue Act states:

(1) If the Designated Officer is satisfied, after making such inquiries as are reasonable in the circumstances in relation to a person who has died in the Hospital or whose dead body has been brought into the Hospital that:

(a) the person had, during the person's lifetime, given his or her consent in writing to the removal after the person's death of tissue from that person's body for the purposes of:

(i) its transplantation to the body of a living person; or

(ii) its use for other therapeutic purposes or for medical purposes or scientific purposes; and

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[2] NSW Health PD2005_341 Human Tissue - Use/Retention including Organ Donation, Post Mortem Examination and Coronial Matters, page 15.

[3] NSW Health PD2005_341 Human Tissue - Use/Retention including Organ Donation, Post Mortem Examination and Coronial Matters, page 15.

[4] NSW Health GL2006_021 Human Tissue - Requirements of the Human Tissue Act 1983 in relation to research & use of tissue

(b) the consent had not been revoked,

the Designated Officer may, by instrument in writing, authorize the removal of tissue from that person's body in accordance with terms and any conditions of consent.

(2) An authority under subsection (1) is not to be given in respect of a deceased child.

(3) If the designated officer is not satisfied as to the matters referred to in subsection (1), or the deceased person is a deceased child, and the designated officer is satisfied, after making such inquiries as are reasonable in the circumstances in relation to the deceased person, that:

(a) the deceased person had not, during the person's lifetime, expressed an objection to the removal of tissue from the person's body; and

(b) a senior available next of kin[5] has given his or her consent in writing, or in any other manner prescribed by the regulations, to the removal of the tissue from the person's body,

the designated officer may, by instrument in writing, authorize the removal of tissue from the deceased person's body in accordance with the terms and any conditions of the consent referred to in paragraph (b).

(4) This section does not apply to a deceased child who, immediately before his or her death, was in the care of the State.

5.14.2 Special rules apply under the Human Tissue Act for the removal of tissue from the body of a deceased child in the care of the State or a person in respect of whose death a coroner has jurisdiction.[6]

Transfer of tissue held for anatomical examination

5.15 The holder of a licence to conduct anatomical examinations may transfer tissue from a body that is in their possession for anatomical examination:

5.15.1 to another holder of a licence, or

5.15.2 to an authorized officer of a hospital; or

5.15.3 to an authorized officer of an interstate hospital; or

5.15.4 to any other person approved in writing by the Director-General, subject to such conditions as may be imposed by the Director General,

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[5] Refer to definition of Senior Available Next of Kin below

[6] Refer to relevant NSW Health policies below.

for use for medical or scientific purposes, unless the holder has reason to believe that to do so would be contrary to the wishes of the deceased or the senior available next of kin of the deceased.[7]

Consent

5.15.5 The guiding principle for researchers is that a person's decision to participate in research is to be voluntary, and based on sufficient information and adequate understanding of both the proposed research and the implications of participation in it.[8]

5.15.6 Participation that is voluntary and based on sufficient information requires an adequate understanding of the purpose, methods, demands, risks and potential benefits of the research.[9]

5.15.7 For consent to be valid the following conditions must be met:

(a) The consent must be obtained prior to the procedure to be carried out.

(b) The person giving consent must have the capacity to do so.

(c) Consent must be given freely.

(d) Consent must be specific to the procedure.

(e) The person giving the consent must be informed in broad terms of the procedure which is intended.[10]

5.15.8 Participants are entitled to withdraw from the research at any stage.

5.15.9 Tissue must only be used within the scope of the consent.

5.15.10 Prior to utilising human tissue for medical research, the Hospital must establish clear consent for the procedures that may be applied to the human tissue.

5.15.11 This consent will be established using the Donation Consent Form (**Consent Form**) (**Annexure B)**.

5.15.12 In the event that the original consent is unclear, the Hospital must seek clarification of the Consent Form from.

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[7] Anatomy Act 1977 (NSW), section 11A.

[8] National Statement on Ethical Conduct in Human Research (NHMRC), page 19.

[9] National Statement on Ethical Conduct in Human Research (NHMRC), page 19.

[10] NSW Health PD2005_341 Human Tissue - Use/Retention including Organ Donation, Post-Mortem Examination and Coronial Matters, page 5.

(a) The donor, where the donor is living and arranging to donate their Material to the Hospital for medical research; or

(b) The Senior Available Next of Kin of the deceased immediately following receipt of the human tissue.

5.15.13 When seeking consent, the donor or Senior Available Next of Kin will be provided with:

(a) the necessary Consent Form; and

(b) other information pertinent for the provision of consent.

5.15.14 In the event that a new area of consent arises for example, where it is believed that a research activity will go beyond the established boundaries of consent covered on the Consent Form, the matter must be referred to the Designated Officer and HREC for investigation and advice.

5.15.15 Following investigation, the HREC will:

(a) advise if the activity is or is not covered by the existing Consent Form;

(b) advise if the activity is or is not covered by the consent provided for the relevant Material; and

(c) with due consideration for applicable aspects of research ethics, determine whether the activity in question should or should not be conducted or further consent is required.

5.15.16 If the HREC finds the activity acceptable, but deems it is not covered by the existing consent, the necessary consent must be obtained before conduct of the activity commences.

5.15.17 In reaching its decision, the HREC will determine whether it is appropriate to seek additional consent for the Material, in respect of the activity. As the Hospital wishes to limit anxiety and inconvenience for the Next of Kin, the HREC will only approve the seeking of additional consent of the existing human tissue where:

(a) the Consent Form originally issued in respect of the human tissue did not incorporate coverage of the necessary consent; and

(b) Exceptional circumstances can be clearly established to warrant the establishment of additional consent for an existing human tissue (e.g. a rare genetic trait has been found in existing human tissue).

5.15.18 Where it is deemed appropriate to seek additional consent, this shall be done in accordance with clause 5.15.14 and 5.15.15, after any necessary amendment has been made to the Consent Form.

6 Receipt and Storage of Material

6.1.1 Material must be delivered to the relevant Hospital department for verification and receipting purposes. Material may only be accepted into the Unit Storage Facility by Authorised Receiving Officers.

7 Prohibition of Trading in Tissue

7.1 The *Human Tissue Act* prohibits a person from entering into, or offering to enter into, a contract or arrangement under which any person agrees, for valuable consideration, whether given or to be given to any such person or to any other person:

7.1.1 to the sale or supply of tissue from any such person's body or from the body of any other person, whether before or after that person's death or the death of that other person, as the case may be; or

7.1.2 to the post mortem examination of any such person's body after that person's death or of the body of any other person after the death of that other person.

7.2 This does not apply to:

7.2.1 The sale or supply of tissue if the tissue has been subjected to processing or treatment and the sale or supply is made for the purposes of enabling the tissue to be used for therapeutic purposes, medical purposes or scientific purposes.

7.2.2 The reimbursement of any expenses necessarily incurred by a person in relation to the removal of tissue in accordance with the Act.

7.2.3 Circumstances were Ministerial approval as been granted.

8 Records

8.1 Medical Practitioners and hospital staff must record in the relevant donor patient's medical record information concerning the source, nature and reason for collection of the Material.

8.2 The Designated Officer shall cause to be held a register containing each of the following:

8.2.1 A copy of all relevant Material Transfer Agreements;

8.2.2 A copy of all relevant Material Request Forms;

8.2.3 Copies of submissions to HREC;

8.2.4 Copies of HREC approval;

8.2.5 A register of Materials supplied or transferred, including a description of the Material and the patient number.

8.3 The registers and records shall be maintained by the Designated Officer as per medical records under Hospital Policy.

9 Privacy

9.1 The Hospital must comply with privacy obligations in relation to the collection, use, storage and transfer of the Material. If possible, all Material should be transferred on a de-identified basis. If the Material needs to be able to be traced then only the patient's identification number should be provided to the transferee of the Material.

10 Facility Access

10.1 Access to the Unit (Unit)

10.1.1 The Unit is to be secured at all times. Keys (physical or electronic) to the Unit will only be provided to:

(a) Unit employees;

(b) a Security Officer; and

(c) employee of the Unit contracted cleaning agencies.

10.1.2 Once they have been issued with keys to the Unit, individuals are responsible for ensuring the Unit's remains secure. Units employees who have been issued with keys will be responsible for admitting all other non-key holding users of the facility and will restrict access to:

(a) Unit employees;

(b) Contractors who have engaged by Unit to undertake repairs, general maintenance or safety checks in these facilities; and

(c) Other users as needs require (i.e. emergency services or repairs); and

(d) Other users who are authorised under legislation to gain access in order to perform the official duties of their position.

10.1.3 Contractors (other than contracted cleaners) and other authorised users must be supervised by a Unit employee or Security Officer at all times when in the Unit. Unit employees controlling access to the Unit must ensure appropriate supervision is available prior to granting admittance to these parties.

10.1.4 Under no circumstances are unauthorised persons to be granted access to the Unit at any time. Any attempt to gain unauthorised access to the Unit, whether the attempt is successful or not, will be considered to be in breach of this policy and may be subject to disciplinary action.

10.2 Access to the Material Storage Equipment

10.2.1 Equipment used to store Material (e.g. fridges, specimen tanks) is only to be accessed by Hospital employees. Under no circumstances is any other individual to touch or otherwise access this equipment.

10.2.2 Any attempt to gain unauthorised access to Material storage equipment, whether the attempt is successful or not, will be considered to be in breach of this policy and may be subject to disciplinary action.

11 Material Transfer Agreement

11.1 Material can only be transferred to other institutions and third parities under the terms of the Material Transfer Agreement (**MTA**) at **Annexure C**.

11.2 The MTA governs the transfer of human tissue from the Hospital (**provider**) to a third party (**recipient**) who may wish to use the Material for medical research.

11.3 For the Hospital, the MTA provides control over the distribution of the material, enables it to restrict the use of the material to non-commercial research, and reduces the legal liability of the Hospital for the recipient's use of the material. In addition, the terms of the MTA can help the Hospital to gain access to the results of the research, both for information and insurance purposes and for commercial exploitation.

11.4 Only the [Executive Director] or the [Designated Officer] is authorized to sign an MTA on behalf of The Hospital.

11.5 Under the Material Transfer Agreement, the Tissue may only be used for the stated Permitted Use (as approved by the HREC and the Hospital). As a general rule, Tissue should only be transferred for non-commercial research purposes.

11.6 Tissue must not be transferred for commercial purposes without the prior written consent of the Hospital.

11.7 The licensee must not further transfer the Material without the prior written consent of the Hospital or as agreed under the Material Transfer Agreement.

11.8 If the Hospital agrees to transfer for commercial purposes or the further transfer of the Tissue, then the Hospital should consider additional matters, including:

11.8.1 the Hospital may need to check whether the consent from the patient (from whom the Material was explanted) included the relevant purpose (being a purpose other than non-commercial research);

11.8.2 the additional risks associated with the transfer, for example if the tissue is to be used to create a biological that will be administered to patients, additional regulatory requirements in relation to the biological and the risks of the transfer of biological hazards or risks and potential liability of the Hospital for same;

11.8.3 additional testing of the tissue may be required prior to transfer;

11.8.4 additional recording and tracking of the Material may be required for regulatory liability purposes;

11.8.5 if the licensee is a NSW public health organisation, coverage by the NSW Treasury Managed Fund is acceptable, however, if the licensee is not a NSW public health organisation, the Hospital may require additional indemnities and insurance from the licensee; and

11.8.6 subject to legal restrictions on the payment for Tissue, the Hospital may wish to enter into a joint venture to benefit from any resulting intellectual property and the commercialisation of that intellectual property.

12 What should the HREC do when assessing research applications involving the use of Materials

12.1 The HREC should consider the requirements set out in GI2006_021 Human Tissue - Requirements of the *Human Tissue Act* (in relation to research & use of tissue) in assessing research applications involving the use of Materials.

13 Disciplinary Proceedings

13.1.1 Participation in any activity that directly or indirectly breaches any part of this policy or its underlying principles may result in participants being subject to internal disciplinary proceedings. The Hospital reserves the right to instruct individuals (including staff and visitors) to vacate the Unit and/or premises and will enforce this right through legal means where necessary.

13.1.2 Failure to follow the reasonable directions of supervisors or other Unit employee is considered to be a breach of this policy as is any subsequent action that directly or indirectly undermines the intent of those directions.

13.1.3 Internal disciplinary action will be managed in accordance with the applicable employment agreement or misconduct policy.

14 Transmission of diseases

14.1 The Hospital must comply with relevant policies to minimize the transmission of diseases in collecting, using, storing, supplying and transferring Material, including but not limited to:

14.1.1 NSW Health PD2010_002 Organ Donation and Transplantation - Managing Risks of Transmission of HIV, HCV and HBV; and

14.1.2 occupational health and safety laws and policies.

15 Disposal of Human Tissue

15.1 The Hospital must dispose of and require the recipient of the Material to dispose of the tissue in accordance with all relevant laws.

16 Updating the Policy and Consent Form

16.1.1 The HREC must, in consultation with employees conduct an ongoing review of this Policy and Consent Form. The review will aim to ensure that the Policy and Consent Form:

(a) provides for appropriate consent for all procedures conducted at the Hospital; and

(b) addresses all statutory requirements.

17 Definitions

Authorised Receiving Officers means Hospital employees authorized to receive Material for research, namely [insert].

Consent Form means the consent form approved by The Hospital and the HREC to be completed by each Donor, the legal guardian of the donor or the Senior Available Next of Kin of the Donor, or other legally authorized person or authority, a copy of which is attached as **Annexure B**.

Designated Officer means the person appointed under section 5 of the *Human Tissue Act 1983* to legally authorize all non-coronial post-mortem examinations and the use of tissue removed for the purposes of coronial or non-coronial post-mortems for other therapeutic, medical or scientific purposes, namely [The Director of Clinical Services of the Hospital].

Donor: means the person (being a patient of the Hospital) from whom the Material was taken.

HREC means the Human Research Ethics Committee of The Hospital.

Human Tissue Act means the *Human Tissue Act 1983 (NSW)*.

Material includes:

(a) tissue, blood, bodily fluids or other bio-specimen;

(b) any genetic information extracted from the Material;

(c) any genetic or biochemical or other derivative derived from that tissue, blood or bio-specimen (including but not limited to cells, proteins, DNA, RNA, cloned genes, etc.); and

(d) any progeny, modification or improvements to the Material that a person may develop, directly or indirectly whilst using the Material supplied by The Hospital.

Material Transfer Agreement: means an agreement that governs the transfer of Material from the Hospital to a third transfer party who may wish to use the Material for medical research purposes. A copy of the Material Transfer Agreement for The Hospital is set out in **Annexure C**.

Medical Research: includes activities other than diagnostic, biochemical or pathological examinations performed as a component of patient care, audit type

activities and calibration of equipment. It includes the evaluation of new diagnostic, prognostic or biological in a series of patients.

National Statement means the publication entitled 'National Statement on Ethical Conduct in Human Research' issued by the National Health and Medical Research Council in accordance with the *National Health and Medical Research Council Act 1992 (Cth)* and any Supplementary Notes published by the National Health and Medical Research Council.

non-regenerative tissue means tissue other than regenerative tissue.

Patient: means a patient of the Hospital.

regenerative tissue means tissue that, after injury or removal, is replaced in the body of a living person by natural processes of growth or repair.

Senior Available Next of Kin has the same meaning as in the *Human Tissue Act* and the *Anatomy Act*, namely:

(aa) in relation to a child who is living:

(i) a parent of the child; or

(ii) if no person referred to in subparagraph (i) is available - the person who is a guardian of the child; and

(a) in relation to a deceased child;

(i) a parent of the child;

(ii) where a parent of the child is not available - a brother or sister of the child, being a brother or sister who has attained the age of 18 years; or

(iii) where no person referred to in subparagraph (i) or (ii) is available - a person who was a guardian of the child immediately before the death of the child; and

(b) in relation to any other deceased person:

(i) a person who was a spouse of the deceased person immediately before the deceased person's death;

(ii) where the deceased person, immediately before death, had no spouse or where the deceased person had a spouse but the person who was then the deceased's spouse is not available - a son or daughter (if any) of the deceased person, being a son or daughter who has attained the age of 18 years;

(iii) where no person referred to in subparagraph (i) or (ii) is available - a parent of the deceased person; or

(iv) where no person referred to in subparagraph (i), (ii) or (iii) is available - a brother or sister of the deceased person, being a brother or sister who has attained the age of 18 years.

spouse means:

(a) a husband or wife; or

(b) the other party to a de facto relationship within the meaning of the *Property (Relationships) Act 1984*,

but where more than one person would so qualify as a spouse, means only the last person so to qualify.

supply has the same meaning as in the *Human Tissue Act*, namely to supply by way of sale, exchange or gift, and includes receive, keep, store for the purpose of supply.

tissue has the same meaning as in the *Human Tissue Act*, namely includes an organ, or part, of a human body and a substance extracted from, or from a part of, the human body.

Unit: means the relevant Unit of The Hospital at which the Material is explanted and stored.

18 NSW Health Guidelines and other guidelines

The following documents are relevant to this Policy:

18.1 Legislation (in alphabetical order)

18.1.1 Anatomy Act 1997 (NSW)

18.1.2 Coroners Act 2009 (NSW)

18.1.3 Health Records and Information Privacy Act 2002 (NSW)

18.1.4 Human Tissue Act 1983 (NSW);

18.1.5 Privacy Act 1988 (Commonwealth)

18.1.6 Therapeutic Goods Act 1989 (Commonwealth)

18.2 NHMRC Guidelines

18.2.1 National Statement on Ethical Conduct in Human Research (2007) (**National Statement**) - Australian Government, National Health and Medical Research Council, Australian Research Council, Australian Vice-Chancellor's Committee, the Council of Australia's University Presidents.

18.2.2 NSW Supplement to the National Statement

18.2.3 Challenging Ethical issues in Contemporary Research in Human Beings (2006).

18.2.4 Australian Government National Health Medical Research Council (NHMRC) - 'Organ and Tissue Donation by Living Donors' Guidelines for ethical practice for health professionals.

18.2.5 Keeping Research on Track (a guide for Aboriginal and Torres Strait Islander peoples about Health Research Ethics).

18.2.6 Making a decision about Organ and Tissue after Death.

18.2.7 Making a decision about organ and tissue donation.

18.3 Code of Ethical Standards for Catholic Health and Aged Care Services in Australia (2001)

18.4 **NSW Guidelines** (in numerical order)

18.4.1 NSW Health - Guidelines for End-of-life Care and Decision-making (PD_2005_057)

18.4.2 NSW Health - Human Tissue - Use/Retention including Organ Donation, Post-Mortem Examination and Coronial Matters (PD2005_341)

18.4.3 NSW Health - Intellectual Property Arising from Health Research - Policy - NSW Department of Health (PD 2005_370)

18.4.4 NSW Health - Consent to Medical Treatment - Patient Information PD (2005_406)

18.4.5 NSW Health - Human Tissue - Consent to Removal of Regenerative Tissue from Young Children and Consent Form (PD2006_010)

18.4.6 NSW Health - Human Tissue - Requirements of the *Human Tissue Act 1983* in relation to research and use of tissue (GL2006_021)

18.4.7 NSW Health - Organ Donation after Cardiac Death (GL2007_012)

Please note that this policy and the list of relevant materials must be updated on a periodical basis. Any reference to legislation, policy or guideline is a reference to that document as amended, updated, superseded or replaced from time to time.

Annexure A

Material Request Form

All requests are managed via the Research Office, St Vincent's Hospital.

Annexure B

St Vincent's Hospital Human Tissue Donation Consent Form

[Note; must comply with NSW Health Policy Directive PD2005_341 Human Tissue-Use/Retention Including Organ Donation, Post-Mortem Examination and Coronial Matters.]

Current HREC approved Participant Information Sheet and Consent Form as available on the Research Office website.

Annexure C

Material Transfer Agreement (MTA)

[insert site logo]

Material Transfer Agreement

Table of contents

Parties

The party listed as the Licensor in Schedule 1 (**Licensor**)

The party listed as the Licensee in Schedule 1 (Licensee)

Background

A The Licensor operates the Facility.

B Medical practitioners at the Facility perform surgery and the Facility is the recipient of explanted human tissue which is donated by patients who are admitted to the Hospital.

C The Licensee seeks access to the Material for the Permitted Use.

D The Licensor has agreed to supply the Material on the terms and conditions of this Agreement to the Licensee and the Licensee agrees to be bound by such terms and conditions.

Operative provisions

1 Term

1.1 The Licence will commence on the Commencement Date and continue until the Termination Date subject to the terms and conditions of this Agreement (**Term**).

2 Licence of Human Tissue

Tissue Request form

2.1 If the Licensee requires Material for the Permitted Use it may provide to the Licensor a Material Request Form in the form of Annexure A.

Supply at discretion of Licensor

2.2 In consideration of the obligations of the Licensee set out below, at the absolute discretion of the Licensor, the Licensor may supply to the Licensee such Material as to be determined by the Licensor depending upon:

2.2.1 the information provided by the Licensee in the Material Request Form;

2.2.2 the availability of the Material explanted from patients of the Facility; and

2.2.3 the requirements of the Licensee and other research institutes.

2.3 Nothing in this Agreement prevents the Licensor from exploiting, distributing or otherwise making the Material available to any other parties at any time.

Collection

2.4 The Licensee must collect or arrange for the collection of the Materials from the Facility at the Licensee's own cost. All risk the Materials transfers to the Licensee upon collection.

2.5 The Licensee must at all times keep the Materials secure and confidential.

Ownership

2.6 Despite any right or permission granted under this Agreement, the Licensor retains ownership of the legal and beneficial rights in the Material.

Meeting with research institutes

2.7 The Licensor may consult with the Licensee, and other research institutes who wish to have access to the Material, to determine what type of Material each research institute would like to have access to. In such a case at least five Business Days notice will be provided.

2.8 The Licensee will use its reasonable endeavours to attend such meetings.

Licence to use

2.9 The Licensor grants to the Licensee a non-exclusive licence to use the Material supplied by the Licensor under this Agreement for the Term for the sole purpose of the Permitted Use, subject to the terms and conditions of this Agreement.

[Choose appropriate option in Schedule 1]

[*Option 1: Further transfer restricted*]

2.10 The right and licence to use the Material is not transferable. The Licensee agrees that the Material may only be used by the Licensee and only in the Research Premises under the direct supervision of the Principal Investigator.

[or]

[Option 2: Further transfer permitted]

2.11 The Licensor grants to the Licensee a non-exclusive licence to use the Material supplied by the Licensor under this Agreement for the Term for the sole purpose of the Permitted Use, subject to the terms and conditions of this Agreement. The Licensee may further transfer some or all of the Material provided that:

2.11.1 the Material is only used for the Permitted Use;

2.11.2 the Material is only transferred to persons approved by the Licensor in writing;

2.11.3 the Licensee remains liable to comply with this Agreement in relation to the Material; and

2.11.4 the Licensee must enter into an agreement with any transferees of the Material/sub-licensees on terms and conditions substantially similar to this Agreement.

Conditions of use and restrictions

2.12 The Licensee must **not**:

2.12.1 use the Material for any purpose other than the Permitted Use;

2.12.2 use the Material for commercial purposes, except with the prior written consent of the Licensor;

2.12.3 use the Material in human subjects, clinical trials or diagnostic purposes involving human subjects, except with the prior written consent of the Licensor;

2.12.4 use the Material for in vivo testing, except with the prior written consent of the Licensor;

2.12.5 use the Material on or in human subjects; or to create products for use on or in human beings without the Licensor's prior written consent. The Licensor may attach conditions to its consent in its absolute discretion.

2.12.6 allow the Material to be used by any person other than the Licensee or a person approved by the Licensor in writing;

2.12.7 use the Material at any place other than at the Research Premises, except with the prior written consent of the Licensor;

2.12.8 export the Material from Australia without the prior written consent of the Licensor;

2.12.9 use the Material to create a product for human use or consumption;

2.12.10 sell, loan or licence the Material to any third party except with the Licensors prior written approval; or

2.12.11 dispose of the Material other than in accordance with the Policies for the disposal of human tissue.

2.13 The Licensee must ensure that the Material is not given (for consideration or otherwise) to any person other than employees of the Licensee or a person approved by the Licensor in writing.

2.14 The Licensee must comply with and must ensure that any person who uses, transports and uses the Material in accordance with this Agreement complies with all applicable laws, Policies and codes of conduct.

2.15 The Licensee must comply and ensure that others using the Material in accordance with this Agreement comply with the Conditions of Use.

2.16 The Licensee must, and must ensure its employees and agents and all people to receive the Material with the approval of the Licensor treat the Material with respect and dignity.

2.17 When the Research is complete, the Licensee must return all excess samples and derivatives of the Material to the Licensor as soon as possible after the completion of the Research.

2.18 The Licensee must make an additional application to store the Material for future use.

2.19 The Licensee must obtain the approval of the HREC for the Research and for the future storage and use of the Material and before tissue banks may be established.

Reporting requirements

2.20 The Licensee must ensure that the Licensee makes a full report to the Licensor about:

2.20.1 any findings, discoveries or results made in the Research;

2.20.2 any findings made in the course of the Research that have implications for the health or welfare of the Donor or any person related to the Donor; and

2.20.3 copies of abstracts, publications or presentations about the Research.

Adverse event reporting to Facility

2.21 The Licensee must notify the Licensor of all Adverse Events involving the Material, as soon as possible, of becoming aware of the Adverse Event.

3 Governance

Regulatory requirements

3.1 The Licensee must ensure that the Material is used in accordance with:

3.1.1 the terms of the Protocol;

3.1.2 the Policies;

3.1.3 conditions imposed by the HREC;

3.1.4 *Therapeutic Goods Act 1989* (Cth);

3.1.5 *Therapeutic Goods Regulations 1990* (Cth);

3.1.6 Guidelines for Good Clinical Practice referred to in regulation 12AB(2)(a) of the *Therapeutic Goods Regulations 1990* (Cth);

3.1.7 The National Statement;

3.1.8 *Privacy Act 1988* (Cth) and any other applicable laws governing the protection and privacy of personal information;

3.1.9 ICH GCP;

3.1.10 in accordance with The Catholic Code of Ethics ;

3.1.11 World Medical Association Declaration of Helsinki entitled 'Ethical Principles for Medical Research Involving Human Subjects'; and

3.1.12 any other legislation or guidelines relating to human tissue, organ donation, therapeutic goods or devices, research and clinical trials from time to time in force.

Where Protocol inconsistent with this Agreement

3.2 Should there be any inconsistency between the Protocol and the terms of this Agreement, the terms of this Agreement prevail.

4 Obligations of the parties

HREC, MAC and other approvals for Research

4.1 Prior to the initiation of the Research (as relevant), the Licensee must obtain all necessary approvals from the HREC, the Facility's Medical Advisory Committee and the relevant department head at the Facility.

TGA approvals for Permitted Use

4.2 The Licensee must obtain all relevant approvals from the TGA or other regulatory authorities to conduct the Permitted Use.

Donor recruitment

4.3 The Licensee must assist the Facility to:

4.3.1 ensure each person that is a Donor (or that person's legally authorised representative) is provided with a Donor Information Sheet and Consent Form for review prior to the donation of the Material;

4.3.2 obtain from each Donor (or from that person's legally authorised representative), a signed and dated Consent Form; and

4.3.3 inform Donors that the Research or Permitted Use is being conducted subject to the National Statement (as relevant to the Permitted Use).

Donor identification

4.4 The Licensee, in dealing with the Material, will not use or disclose the identity the Donor without HREC approval.

5 Cost recovery

5.1 The Licensee must pay the Costs plus any applicable GST to the Licensor upon receipt of an invoice from the Licensor.

5.2 The parties acknowledge that the Costs is an amount to recover the reasonable costs associated with the removal, evaluation, storage, processing and distribution of the Material in accordance with the Human Tissue Act 1983 (NSW).

6 Goods and services tax

Recovery of GST on supplies and adjustments under this agreement

6.1 All consideration provided under this agreement is exclusive of GST, unless it is expressed to be GST-inclusive.

6.2 Where a party (**Supplier**) makes a taxable supply to another party (**Recipient**) under or in connection with this agreement, the Recipient must pay to the Supplier an additional amount equal to the GST payable on the supply (unless the consideration for that taxable supply is expressed to include GST). The additional amount must be paid by the Recipient at the later of the following:

6.2.1 the date when any consideration for the taxable supply is first paid or provided; and

6.2.2 the date when the Supplier issues a tax invoice to the Recipient.

6.3 If, under or in connection with this Agreement, the Supplier has an adjustment for a supply under the GST law which varies the amount of GST payable by the Supplier, the Supplier will adjust the amount payable by the Recipient to take account of the varied GST amount. The Supplier must issue an adjustment note to the Recipient within 28 days of becoming aware of the adjustment.

Other GST matters

6.4 If a party is entitled to be reimbursed or indemnified under this Agreement, the amount to be reimbursed or indemnified is reduced by the amount of GST for which there is an entitlement to claim an input tax credit on an acquisition associated with the reimbursement or indemnity. The reduction is to be made before any increase under clause 6.2. An entity is assumed to be entitled to a full input tax credit on an acquisition associated with the reimbursement or indemnity unless it demonstrates otherwise before the date the reimbursement or indemnity is made.

6.5 Any reference in this Agreement to sales, revenue, income, value or similar amount (**Revenue**) is a reference to that Revenue exclusive of GST (unless that Revenue is expressed to be GST-inclusive).

6.6 Any reference in this agreement to cost, expense, liability or similar amount (**Expense**) is a reference to that Expense exclusive of GST (unless that Expense is expressed to be GST-inclusive).

6.7 This clause will not merge on completion and will survive the termination of this Agreement by any party.

6.8 Terms used in this clause that are not otherwise defined in this Agreement have the meanings given to them in the GST Act.

7 Indemnity and Insurance

Limitation of liability

7.1 The Licensee acknowledges that the Material is experimental and may have hazardous properties (including infectious diseases).

7.2 The Licensor accepts no responsibility for the transmission of any disease as a result of the use of any Material supplied by the Licensor.

7.3 The Licensee acknowledges that it uses the Material at its own risk and agrees to accept sole responsibility and liability for the conduct of the Research.

7.4 To the extent permitted by law, the Licensor excludes all warranties (express or implied), including warranties as to the merchantability and fitness for a particular purpose.

7.5 The Licensor does not warrant that the Licensee will receive any Material or the type or quality or fitness for purpose of the Research.

7.6 The Licensor makes no representation that the use of the Material will not infringe any third party intellectual property rights.

7.7 To the extent prohibited by law, the Licensee assumes all liability for loss or damage arising from the possession, handling, storage, use, transport and disposal of the Material by the Licensee.

7.8 All other conditions and warranties of any type in relation to the Material are excluded to the maximum extent allowed by the law.

7.9 A 'Non-excludable Condition" is an implied condition or warranty the exclusion of which from a contract would contravene any statute or causes any part of this Agreement to be void. Notwithstanding any other provision of this Agreement, nothing in this Agreement excludes, restricts or modifies any Non-excludable Condition. The Licensor's liability for a breach of any Non-excludable Condition (other than one implied under section 69 of the Trade Practices Act 1974) is limited, at the Licensor's option to any one of:

7.9.1 If the breach relates to goods:

(a) the replacement of the goods or the supply of equivalent goods:

(b) the repair of such goods;

(c) the payment of the cost of replacing the goods or of acquiring equivalent goods; or

(d) the payment of the cost of having the goods repaired; and

7.9.2 If the breach relates to services:

(a) the supplying of the services again; or

(b) the payment of the cost of having the services supplied again.

7.10 The Licensee will be liable for and indemnify and hold harmless the Licensor, its officers, employees and agents against all liability, damages, loss, expense, cost and proceedings of any nature whatsoever as a result of each or any one of the following:

7.10.1 its acceptance, use and disposal of the Material;

7.10.2 the conduct of the Research and the Permitted Use;

7.10.3 any negligence or wilful default or breach of this Agreement or breach of statute of the Licensee or its employees or other people to whom the Licensee has transferred the Materials.

7.11 A party's liability under an indemnity in this Agreement will be reduced by the loss, damage or injury caused or contributed by the party being indemnified (or its employees, agents, officers and contractors) to the extent of their contribution.

7.12 The Licensor has no liability whatsoever (whether in contract, tort including negligence, pursuant to statute or otherwise) to the Licensee, to people to whom the Licensee has transferred the Materials, their officers, employees and agents for any loss, costs, loss of profits, liability to any third party, or any indirect or consequential loss or damage whatsoever arising out of or in relation to this Agreement.

7.13 This clause shall survive the termination of this Agreement.

Insurance

7.14 If the Licensee is a NSW public health organisation (as defined in the Health Services Act 1997 (NSW)), the Licensee (through the New South Wales Department of Health) participates in the New South Wales Government's Treasury Managed Fund, being a scheme covering all insurable risks of the New South Wales Department of Health. The Licensee shall, subject to any changes in applicable New South Wales law and government policy, maintain its participation in the Treasury Managed Fund through the term of this Agreement and for at least three years following termination of this Agreement to cover any claims arising from this Agreement.

7.15 If the Licensee is not a NSW public health organisation (as defined in the Health Services Act 1997 (NSW)), the Licensee will effect and maintain appropriate insurance cover to the satisfaction of the Licensor in respect of its liability under this Agreement and such cover shall be for a minimum of $AUD10,000,000 in respect of any one occurrence or series of occurrences arising from one event.

7.16 The Licensee will provide documentary evidence of such insurance cover upon request by the Licensor.

Indemnity survives

7.17 The indemnity in this clause 7 shall survive termination of this Agreement.

8 Confidentiality

Non-disclosure of confidential information

8.1 A party to this Agreement must not disclose to any third party, without the prior written consent of the other parties, any Confidential Information provided from the other. This obligation does not extend to information which:

8.1.1 is, or becomes public knowledge without the fault of the receiving party;

8.1.2 is, or becomes available to the receiving party from a source other than the disclosing party; or

8.1.3 is independently developed by the receiving party.

Non-disclosure of this Agreement

8.2 No party to this Agreement may, without the prior written consent of the other parties, provide to any other person a copy of this Agreement or any provision hereof or disclose the contents of this Agreement or any provision of it to any other person

except as is necessary for the performance of this Agreement or required to obtain legal or financial advice.

Disclosure permissible to comply with law

8.3 Notwithstanding clauses 8.1 and 8.2, a party may release information necessary to conform to all applicable laws and regulations.

Confidentiality obligations survive

8.4 The obligations of confidentiality referred to in this clause 8 shall survive the termination of this Agreement.

9 Termination

Termination for convenience

9.1 Either party may terminate this Agreement at any time by giving 30 days written notice to the other party.

Termination for default

9.2 Either the Licensee or the Licensor (**Terminating Party**) may terminate this Agreement with immediate effect if the other party (**Defaulting Party**) is:

9.2.1 in material breach of any of the Defaulting Party's obligations under this Agreement and fails to remedy such breach where it is capable of remedy within 14 days of a written notice from the Terminating Party specifying the breach and requiring its remedy; or

9.2.2 declared insolvent or has an administrator or receiver appointed over all or any part of its assets or ceases or threatens to cease to carry on its business.

Termination in interests of Patients

9.3 A party may terminate this Agreement on written notice with immediate effect if it is reasonably of the opinion that the Research or the Permitted Use should cease in the interests of the public or patients.

Termination where harm to reputation

9.4 The Licensor may terminate this Agreement on written notice with immediate effect if it is reasonably of the opinion that continuing the Research or Permitted Use would cause harm to its reputation.

Co-operation upon termination

9.5 Upon receipt of notice of termination, the Licensee will comply with the reasonable directions of the Licensor as to the return or destruction of the Material and Confidential Information provided by the Licensor.

9.6 Material destroyed under this Agreement must be disposed of in the manner required by the Policies, the NHMRC National Statement on Ethical Conduct in Human Research 2007 or any other manner directed by the Licensor.

Termination does not affect rights in respect of antecedent breach

9.7 Termination of this Agreement pursuant to this clause 9 will not affect the rights of either party in respect of any antecedent breach of this Agreement

10 Publicity

10.1 The Licensee must not use the name of the Facility, nor any member of the Facility's staff, in any publicity, advertising or news release without the prior written approval of an authorised representative of the Facility.

11 Intellectual property

IP and Know How of Licensor

11.1 All Intellectual Property Rights and Know How owned by the Licensor prior to the date of the Agreement is and shall remain the property of the Licensor.

11.2 Except as provided in this Agreement, the Licensee agrees that it has no express or implied licence or other right to any Intellectual Property Rights of the Licensor. In particular, no express or implied licence or other right is provided to use the Materials for commercial purposes, including without limitation, research funded partially or wholly by any commercial entity.

IP and Know How of Licensee

11.3 All Intellectual Property Rights and Know How owned by the Licensee prior to the date of the Agreement shall remain the property of the Licensee.

11.4 The fact that the Licensee has used the Materials for research and experimentation pursuant to this Agreement will not give the Licensor any right, title or interest in any product or process that is developed or invented by the Licensee in the course of that research or experimentation and subject to clause 11.5, the Licensee will own all Intellectual Property Rights in any product or process that is developed or invented by the Licensee in the course of that research or experimentation.

11.5 However, if:

11.5.1 that product or process incorporates or uses information or material which is confidential to the Licensor or any patented or patentable invention which is the subject of a registration or application in the name of the Licensor or its Related Bodies Corporate or third party licensees, then the Licensee will not have the right to use such information, material or invention in the commercial exploitation of the relevant product or process; and

11.5.2 If the Licensee breaches it's obligations under this Agreement in using the Materials for commercial purposes, the Licensor reserves its rights, including but not limited to seeking interlocutory relief and the right to compensation for its contribution to the product or process developed as a result of the Research.

Publication and Acknowledgement

11.6 The Licensee must ensure that the Licensor is acknowledged in any publication or presentation about the Research as follows:

11.6.1 "*The biospecimen used in this project was provided by [insert name of Licensor] with appropriate ethics approval. We acknowledge the contribution of St Vincent's Hospital to this research project*."

11.7 The Licensee must not Publish any Publication containing or referring to any Materials without the prior written consent of the Licensor.

11.8 The Licensee must give notice of any proposed Publication drafted by them and/or other personnel involved in the conduct of the Research to the Licensor at least 40 days before any forwarding to a party that is not bound by the confidentiality obligations set out in clause 8.

11.9 The Licensor may, within that 40-day period do any one or more of the following:

11.9.1 provide comments on the proposed Publication to the Licensee, in which case the Licensee must consider such comments but will not be bound to follow them;

11.9.2 request delay of Publication for no more than 120 days to allow the Licensor to file register patent applications or take other measures to preserve its proprietary rights, in which case the Licensee must abide by that request;

11.9.3 request that the Licensee remove specified Confidential Information (other than the results of the Research) from the Publication, in which case the Licensee must remove such specified Confidential Information as is reasonably required to protect the Intellectual Property of the Licensor.

11.10 If the Licensee has not received any comments from the Licensor on the proposed Publication within 40 days of giving notice to the Licensor under clause 11.8, the Licensee may proceed to make the Publication.

11.11 Where the Licensee intends to Publish the method, results or conclusions from the Research, any person named as an author on that Publication or otherwise noted as the Principal Investigator or an investigator of the Research in the Publication, will be given a reasonable opportunity to review the Publication and request the removal of his or her name from the Publication and the Licensee shall comply with any such request.

12 Relationship between the parties

Independent contractors

12.1 The parties to this Agreement are independent contractors and nothing in this Agreement creates a relationship of employer and employee, principal and agent, joint venture or partnership between the parties.

13 Dispute resolution process

Dispute notice

13.1 If the parties are unable to agree on any matter under this Agreement either of them may give written notice to the other stating details of the matter in dispute and requiring that the matter be resolved by a meeting between the parties.

Meeting within 7 days of dispute notice

13.2 The parties must meet in good faith to seek to resolve any area of dispute. The parties must meet together within seven days of the serving of notice of a dispute under this Agreement.

Referral to ACDC for mediation

13.3 If the parties cannot resolve the dispute within seven days of the initial meeting as set out in clause 13.2, the parties agree to refer the dispute to mediation established in accordance with the rules of the Australian Commercial Dispute Centre Limited.

Sharing of costs

13.4 The parties agree to meet the costs of their own representation and to share equally in the costs incurred by the mediation being conducted.

Parties to continue to perform pending dispute resolution

13.5 Pending determination of any dispute under this Agreement the parties agree to continue to perform all their obligations under this Agreement.

Interlocutory relief

13.6 This clause 13 shall not prohibit a party from seeking urgent interlocutory relief from the Courts if that party will incur irreparable harm if not permitted to do so.

14 Notices

Giving notices

14.1 Any notice or communication given to a party under this Agreement is only given if it is in writing and sent in one of the following ways:

14.1.1 Delivered or posted to that party at its address and marked for the attention of the relevant department or officer (if any) set out in Schedule 1.

14.1.2 Faxed to that party at its fax number and marked for the attention of the relevant department or officer (if any) set out in Schedule 1.

Change of address or fax number

14.2 If a party gives the other party three business days notice of a change of its address or fax number, any notice or communication is only given by that other party if it is delivered, posted or faxed to the latest address or fax number.

Time notice is given

14.3 Any notice or communication is to be treated as given at the following time:

14.3.1 If it is delivered, when it is left at the relevant address.

14.3.2 If it is sent by post, two (or, in the case of a notice or communication posted to another country, nine) business days after it is posted.

14.3.3 If it is sent by fax, as soon as the sender receives from the sender's fax machine a report of an error free transmission to the correct fax number.

14.4 However, if any notice or communication is given, on a day that is not a business day or after 5pm on a business day, in the place of the party to whom it is sent, it is to be treated as having been given at the beginning of the next business day.

15 Miscellaneous

Approvals and consents

15.1 Unless this Agreement expressly provides otherwise, a party may give or withhold an approval or consent in that party's absolute discretion and subject to any conditions determined by the party. A party is not obliged to give its reasons for giving or withholding a consent or approval or for giving a consent or approval subject to conditions.

15.2 Where this Agreement refers to a matter being to the 'satisfaction' of a party, this means to the satisfaction of that party in its absolute discretion.

Assignments and transfers

15.3 A party must not assign or transfer any of its rights or obligations under this Agreement without the prior written consent of each of the other parties.

Stamp duty and Costs

15.4 Except as otherwise set out in this Agreement, each party must pay its own costs and expenses for preparing, negotiating, executing and completing this Agreement and any document related to this Agreement.

15.5 The Licensee must pay any stamp duty in relation to this Agreement.

Entire agreement

15.6 This Agreement contains everything the parties have agreed in relation to the subject matter it deals with. No party can rely on an earlier written document or anything said or done by or on behalf of another party before this Agreement was executed.

Execution of separate documents

15.7 This Agreement is properly executed if each party executes either this document or an identical document. In the latter case, this Agreement takes effect when the separately executed documents are exchanged between the parties.

Further acts

15.8 Each party must at its own expense promptly execute all documents and do or use reasonable endeavours to cause a third party to do all things that another party from time to time may reasonably request in order to give effect to, perfect or complete this Agreement and all transactions incidental to it.

Governing law and jurisdiction

15.9 This Agreement is governed by the law of the Territory. The parties submit to the non-exclusive jurisdiction of its courts and courts of appeal from them. The parties will not object to the exercise of jurisdiction by those courts on any basis.

Joint and individual liability and benefits

15.10 Except as otherwise set out in this Agreement, any covenant, agreement, representation or warranty under this Agreement by two or more persons binds them jointly and each of them individually, and any benefit in favour of two or more persons is for the benefit of them jointly and each of them individually.

Severability

15.11 Each provision of this Agreement is individually severable. If any provision is or becomes illegal, unenforceable or invalid in any jurisdiction it is to be treated as being severed from this Agreement in the relevant jurisdiction, but the rest of this Agreement will not be affected. The legality, validity and enforceability of the provision in any other jurisdiction will not be affected.

Variation

15.12 No variation of this Agreement will be of any force or effect unless it is in writing and signed by each party to this Agreement.

Waivers

15.13 A waiver of any right, power or remedy under this Agreement must be in writing signed by the party granting it. A waiver only affects the particular obligation or breach for which it is given. It is not an implied waiver of any other obligation or breach or an implied waiver of that obligation or breach on any other occasion.

15.14 The fact that a party fails to do, or delays in doing, something the party is entitled to do under this Agreement does not amount to a waiver.

16 Definitions and interpretation

Definitions

16.1 In this Agreement the following definitions apply:

Adverse Event means the same in the relevant adverse event reporting policy of the Licensor.

Agreement means this document and includes any Schedules or Annexures to this document.

Business Day means a day other than a Saturday or Sunday or a public holiday in the Territory.

Commencement Date means the commencement date stated in Schedule 1.

Conditions of Use mean the conditions of use as set out in this Agreement.

Confidential Information means confidential information of a party and includes information whether verbal, written or in some other form, including but not limited to electronic form relating to:

the Research and Permitted Use;

the Material and all documents, records and reports and other information relating to the Material;

(a) knowledge or information regarding the business transactions, affairs, property, policies, processes or activities of the other party;

(b) any document which is marked confidential;

(c) any document, tangible item or information which a party advises the other party is confidential or that each party should know or realise is confidential; and

(d) the medical records of the Donors.

Consent Form means the consent form approved by the Facility and the HREC to be completed by each Donor or a relative of the Donor, the legal guardian of the Donor or other legally authorised person or authority.

Costs means the costs specified in Schedule 1, exclusive of GST.

Donor means the person from whom the Material was taken.

Donor Information Sheet means the document that has been approved by the Licensor and the HREC that explains the process for the donation of the Material and the use of that Material in research activities, and for living Donors, the risks associated with the Donation, in plain English language.

Facility means the facility named in Schedule 1.

GST means:

the same as in the GST Act; and

(e) any amounts imposed as additional tax, penalty tax, fine, interest or other charge payable in respect of GST as defined in paragraph (a).

GST Act means *A New Tax System (Goods and Services Tax) Act 1999* (Cth).

HREC means the Human Research Ethics Committee that is responsible for reviewing medical research and clinical trial protocols for the Facility named in Item 11 of Schedule 1.

ICH GCP means the ICH Harmonised Tripartite Note for Guidance on Good Clinical Practice (CPMP/ICH/135/95) to the extent that the TGA has adopted CPMP/ICH/135/95 as explained in the TGA publication entitled 'Note for Guidance on Good Clinical Practice (CPMP/ICH/135/95) – Annotated with TGA Comments' published in July 2000.

Intellectual Property Rights means patents, trademarks, copyrights, trade secrets, Know How, topography rights, rights to extract information from a database, design rights, rights to keep Know How confidential and all rights or forms of protection of a similar nature or having equivalent or similar effect to any of them which may subsist anywhere in the world, whether or not any of them are registered and including applications for registration of any of them.

Know How means all technical and other information which is not in the public domain, including but not limited to information comprising or relating to concepts or discoveries, data, designs, formulae, ideas, inventions, methods, models, procedures, designs for experiments and tests and results of experimentation and testing, processes, specifications and techniques, laboratory records, clinical data, manufacturing data, and information contained in submissions to regulatory authorities.

Material means:

patient tissue, blood, bodily fluids or other bio-specimen specified in the Schedule;

any genetic information extracted from the Material;

any genetic or biochemical or other derivative derived from that tissue, blood or bio-specimen (including but not limited to cells, proteins, DNA, RNA, cloned genes, etc.); and

any progeny, modification or improvements to the Material that the Licensee may develop, directly or indirectly whilst using the Material supplied by the Licensor.

Material Request Form means the Material Request Form as set out in Annexure A.

National Statement means the publication entitled 'National Statement on Ethical Conduct in Research Involving Humans' issued by the National Health and Medical Research Council in accordance with the National Health and Medical Research Council Act 1992 (Cth) and any Supplementary Notes published by the National Health and Medical Research Council.

New Intellectual Property Rights means and Intellectual Property Rights created by the Licensee in relation the Material or arising out of the Research after the Commencement Date.

Permitted Use means the permitted use of the Materials (by the Licensee or a permitted transferee of the Material) as set out in Annexure A.

Policies means the policies and procedures of the Licensor as listed in Annexure B and as notified by the Licensor to the Licensee from time to time.

Principal Investigator means the Principal Investigator (being an employee or contractor to the Licensee) named in the Schedule.

Protocol means the Protocol to govern the management of the Material and Research as prepared by the Licensee and approved by the Licensor in writing from time to time.

Publish means to publish by way of a paper, article, manuscript, report, poster, internet posting, presentation slides, abstract, outline, video, instruction material or other disclosure of Study Materials, in printed, electronic, oral or other form. **Publication** has a corresponding meaning.

Research means the research for which the Material will be used as specified in Schedule 1.

Research Premises means the premises at which the Research is to be conducted, specified in Schedule 1.

Schedule means Schedule 1 to this Agreement.

Termination Date means the termination date stated in Schedule 1.

Territory means the Australian State or Territory identified in Schedule 1.

TGA means the Therapeutic Goods Administration, a division of the Commonwealth Department of Health and Ageing.

Interpretation

16.2 In the interpretation of this Agreement, the following provisions apply unless the context otherwise requires:

16.2.1 Headings are inserted for convenience only and do not affect the interpretation of this Agreement.

16.2.2 If the day on which any act, matter or thing is to be done under this Agreement is not a business day, the act, matter or thing must be done on the next business day.

16.2.3 A reference in this Agreement to 'dollars' or '$' means Australian dollars and all amounts payable under this Agreement are payable in Australian dollars.

16.2.4 A reference in this Agreement to any law, legislation or legislative provision includes any statutory modification, amendment or re-enactment, and any subordinate legislation or regulations issued under that legislation or legislative provision.

16.2.5 A reference in this Agreement to any document or agreement is to that document or agreement as amended, novated, supplemented or replaced.

16.2.6 A reference to a clause, part, schedule or attachment is a reference to a clause, part, schedule or attachment of or to this Agreement.

16.2.7 An expression importing a natural person includes any company, trust, partnership, joint venture, association, body corporate or governmental agency.

16.2.8 Where a word or phrase is given a defined meaning, another part of speech or other grammatical form in respect of that word or phrase has a corresponding meaning.

16.2.9 A word which indicates the singular also indicates the plural, a word which indicates the plural also indicates the singular, and a reference to any gender also indicates the other genders.

16.2.10 A reference to the word 'include' or 'including' is to be interpreted without limitation.

16.2.11 Any schedules and attachments form part of this Agreement.

Execution and date

Executed as an agreement.

Date:

Executed by [**St Vincent's Hospital Limited]**
by its authorised signatory

. . . . .	. . . . .
Signature of witness	Signature of authorised representative
. . . . .	. . . . .
Name of witness (print)	Name of authorised representative (print)

Executed by **[ ]** by its authorised signatory:

. . . . .	. . . . .
Signature witness	Signature of authorised representative
. . . . .	. . . . .
Name of witness (print)	Name of authorised representative (print)

Schedule 1

Agreement Details

1. The parties

1.1. **Licensor**

1.1.1. Name: St Vincent's Hospital

1.1.2. ABN:

1.1.3. Address of for notices:

1.1.4. Fax:

1.2. **Licensee**

1.1.5. Name of Licensee:

1.1.6. ABN of Licensee

1.1.7. Address of Licensee:

1.1.8. Fax:

1.3. Optional clause: Clause 2.10 or 2.11 is to apply (please select).

1.4. Facility: [insert]

1.5. Material: Explanted human tissue as described in the Material Request Form and as approved by the Licensor in writing.

1.6. Costs

1.6.1. [insert]

1.7. Permitted Use of the Material: [Health and medical research]. Note: the Permitted Use must be for research or commercial evaluation purposes. Do not use this Agreement for commercial use other than initial evaluation.

1.8. Research: As set out in the relevant Material Request Form provided by the Licensee to the Licensor and approved by the Licensor from time to time.

1.9. Research Premises: As set out in the relevant Material Request Form

1.10. Commencement Date: the date this Agreement is signed by all parties to it.

1.11. Termination Date: [insert]

1.12. Territory: New South Wales

1.13. HREC: [insert]

Annexure A

Material Request Form

Pursuant to the Human Material Transfer Agreement between St Vincent's Hospital Limited and the Applicant dated [insert]

Name of Applicant:

ABN of Applicant:

Applicant Contact Name:

Application Contact Details:

Telephone:

Fax:

Email

Name of Principal Investigator:

Principal Investigator Contact Details:

Telephone:

Fax:

Email

Description of Proposed Use for the Materials and/or Research Project:

Research Premises:

Date of HREC approval:

Date of Application:

Type of Material requested:

Quantity of Material requested:

Material Management requirements (Packaging, storage, preservation requirements):

Does the Research require patient related data through medical records, outcome data (eg Cancer Council) or other reports? If so, please specify data required and reason:

Does the Research require the ability to store the Material for future use? If so, please explain reasons, how much and what type of tissue or derivative is to be stored and what form and where:

Do you intend to transfer the Material to a third party? If so, please provide details of the other party and the reason for the transfer?

Annexure B

Policies

Policy for the Collection, Use, Supply and Transfer of Material (including Human Tissue) for Medical Research: November 2010

NSW Health GL2006_021 Human Tissue – Requirements of the Human Tissue Act 1983 in relation to research and use of tissue

Occupational health & safety

Building Access and security

Privacy