



Breast Cancer Tissue Bank Material Transfer Agreement

Parties

University	The University of Sydney , a body corporate under the University of Sydney Act 1989, ABN 15 211 513 464, of c/o Westmead Millennium Institute (C24) University of Sydney NSW 2006	
Contact Officer	Attention: Director, Westmead Millennium Institute	Telephone: +61 2 9845 9005
Breast Cancer Tissue Bank Project Officer	Attention: Jane Carpenter , Email: jane_carpenter@wmi.usyd.edu.au	Telephone: +61 2 9845 9006 Fax: 9845 9100
Recipient	«RecipientOrganisation_», ABN [insert ABN], of «RecipientAddress_»	
Recipient Project Officer	Attention: «RecipientName_», Email: «RecipientEmail_»	Attention: «RecipientName_», Email: «RecipientEmail_»

Details

Effective Date	The effective date of this agreement is:
Does the Material include biological materials?	YES
Material (clause 1.1)	All codified materials as listed in Schedule 1 and, any Progeny and any Unmodified Derivatives as applicable but does not include Modifications.
Supply Details (clause 1.1)	[Insert details of when and where the Material and Data will be delivered to the Recipient by the University]
Location (clause 1.2)	[Insert location where Material will be used by the Recipient]
Research Purpose (clause 1.2)	The Research Purpose as described in the approved project description as attached a Schedule 2.
Recipient Personnel (clause 1.2)	[List personnel of Recipient who will be responsible for dealing with the Material]
Ethics Approval (clause 1.2)	The relevant ethics consents as required for the Research Purpose including the following approvals: Human Research Ethics Committee (mandatory) [insert name of HREC and the approval number and/or attach copy of consent form] [insert relevant ethic approval letters or approval numbers for any other ethics approval obtained for Research Purpose]

Data (clause 2)	<ul style="list-style-type: none"> a) any annotated clinical information as requested by the Recipient and approved for release by the BCTB Management Committee; b) any annotated non-clinical data and c) all information or reports received from the University and the personnel of the collaborating institutions in respect of research outcomes or research proposals which may relate the use of the Materials or other projects relevant to the this transfer of Materials to the Recipient and the Research Proposal.
Third Party Rights (clause 4.4)	Third party obligations are currently in place in relation to the Material and/or Data: YES
Expiry Date (clause 7.1)	<p>The earliest of the following:</p> <ul style="list-style-type: none"> a) the conclusion of the Research Purpose; or b) 1 January 2011

Special Terms

Context

The University and its collaborating institutions have entered into funding agreements with the NHMRC, Cancer Institute NSW and the National Breast Cancer Foundation for the purpose of establishing a breast cancer biospecimen resource facility (Breast Cancer Tissue Bank ("BCTB")).

The Recipient acknowledges that the University has entered into these funding agreements which impose certain obligations on the University as the Administering Organisation regarding the use of the Materials and the conduct of research with the Materials.

Special Terms

In recognition of these obligations the Recipient agrees to abide by the terms of this agreement including the following special terms:

1. The Recipient agrees to abide by the BCTB's Access Policy as found at (<https://abctb.org.au/abctb/docs/accessPolicy.pdf>) and all reasonable instructions of the University or the BCTB Management Group in respect to the Materials or the Research Purpose as communicated to the Recipient at the time approval is granted for the Research Purpose or at anytime during the Term of this agreement.
2. Details of the Recipient's use of the Material or Data (including an audit of those Materials used for the Research Purpose, those Materials remaining and their general condition) will be provided by the Recipient to the BCTB in the form of a report (the template for the report to be advised by the BCTB) which will be submitted at 12 month intervals from the date of execution until the earliest of the either of the following occurs:
 - a) the completion of the Research Purpose;
 - b) the Expiry Date; or
 - c) termination of this agreement.

The report may be used by the University and the BCTB without restriction.

3. All findings from the Recipient's use of the Material or Data (including a statement in regards to any New IPRs, Modifications and Recipient New IPRs pursuant to clause 4.3 will be provided by the Recipient to the BCTB in the form of a report which will be submitted when the earliest of the either of the following occurs:
 - (a) publication of results;
 - (b) the completion of the Research Purpose;
 - (c) the Expiry Date; or

(d) termination of this agreement.

4. The Recipient agrees that neither the Material nor accompanying Data will be used either alone or in conjunction with any other information, in any effort whatsoever to establish the individual identities of any subjects from which the Material was derived.

5. Subjects from whom the Material has been derived and provided to BCTB may decide to withdraw consent for use of the Material. In this event, the BCTB will then notify all Recipients of such Material and associated Data for which consent has been withdrawn and request that the Recipients destroy the samples if not already destroyed. Recipient shall destroy such Material and the associated Data which was provided, and shall provide the University and BCTB with certification stating that the Material and Data had been destroyed.

6. The Recipient acknowledges and agrees that the following is confidential information ("Confidential Information"):

- a) Materials and Data;
- b) all other information relating to the Materials provided by University to the Recipient including clinical data such as patient details and patient personal information;
- c) the reports as provided in Special Term 2; and
- d) any documents describing New IPRs

with the exception of information which:

- a) is in or becomes part of the public domain other than through a breach of this agreement; or
- b) the Recipient can prove by contemporaneous written documentation was already known to it at the time of disclosure by the University.

7. The Recipient agrees to keep and maintain all Confidential Information strictly confidential and must use it only for the Research Purpose. The Recipient must not disclose any Confidential Information to any third party without the University's and the BCTB Management Group prior written consent.

8. The Intellectual Property Policy of the BCTB Management Group states that all intellectual property rights (IPRs) arising from the Recipient's use of the Materials and Data will be owned by the parties who created or made an inventive contribution to those IPRs. The Recipient acknowledges this policy and agrees to abide by clause 4 of the General Terms to give effect to this policy. For the avoidance of doubt, all reports submitted to the BCTB under Special Term 3 will be retained for inclusion with the donor records in the BCTB database.

9. The Recipient agrees to acknowledge the BCTB and to appropriately cite by authorship any responsible University or BCTB investigators and staff members in any publications or presentations which result from the Recipient's use of the Materials. The following acknowledgement must appear on all such publications or presentations:

"Tissues and samples were received from the Australia Breast Cancer Tissue Bank which is generously supported by the National Health and Medical Research Council of Australia, The Cancer Institute NSW and the National Breast Cancer Foundation. The tissues and samples are made available to researchers on a non-exclusive basis."

Note: All capitalised terms in column 1 of the Details have the meaning given in column 2.

EXECUTED as an agreement on the terms of the Details, Special Terms and General Terms.

<p>SIGNED for and on behalf of THE UNIVERSITY OF SYDNEY by its duly authorised representative:</p> <p>..... Signature</p> <p>..... Printed Name</p> <p>Position: DIRECTOR (or delegate) Westmead Millennium Institute</p> <p>..... Date</p> <p>In the presence of:</p> <p>..... Signature</p> <p>..... Printed Name</p>	<p>SIGNED for and on behalf of THE RECIPIENT by its duly authorised representative:</p> <p>..... Signature</p> <p>.....Dr Nick Pearce Printed Name</p> <p>.....COOO..... Position</p> <p>..... Date</p> <p>In the presence of:</p> <p>..... Signature</p> <p>..... Printed Name</p>
<p>Note: By executing this agreement each signatory represents that he or she is authorised to sign on behalf of their entity. The effective date of this agreement will be the Effective Date specified in the Details or if no Effective Date is specified in the Details the date on which the agreement has been executed by ALL parties.</p>	

General Terms

1 Material

1.1 Supply

The University, acting on behalf of the BCTB, agrees to supply the Material and the Data to the Recipient for the Research Purpose in accordance with the Supply Details.

1.2 Use

The Recipient agrees to limit the use of the Material and Data so that it is used:

- (a) only at the Location;
- (b) only for the Research Purpose;
- (c) only under the direction of the Recipient Personnel; and
- (d) not for any commercial or profit-making purpose.

1.3 Prohibited Use

The Recipient agrees not to use the Material in human subjects or in clinical trials involving human subjects without the written permission of the University and the BCTB Management Group, such permission to be withheld at the University's and the BCTB Management Group's absolute discretion.

1.4 Compliance with regulations and policy

The Recipient agrees to use, and ensure the use of, the Material and Data in accordance with all applicable statutes, regulations and codes of conduct, including those relating to research involving humans, animals or DNA, and only after first obtaining necessary approvals from its relevant ethics committee(s).

1.5 Limited transfer

(a) The Recipient must not transfer the Material or Data to any other party other than a party working under the direct supervision of the Recipient Personnel at the Location unless it obtains the prior written consent of the University. The Recipient will promptly submit any requests to transfer the Material or the Data to the University for approval, such approval to be withheld in the University's absolute discretion.

(b) Notwithstanding clause 1.5 (a) the Recipient shall have the right, without restriction, to distribute substances created by the Recipient through the use of the Material, only if those substances are not Progeny, Unmodified Derivatives, or Modifications.

1.6 Security and safety measures

The Recipient will establish and implement appropriate policies and procedures to:

- (a) safeguard the Material and the Data against disclosure to other parties with the same degree of care as it exercises with its own materials of a similar nature;
- (b) maintain the Material and Data under appropriate and safe conditions and in accordance with any directions by the University and the BCTB Management Group; and
- (c) keep the Material and Data in such a way that it is clearly identifiable as the property of the BCTB.

2 Data

2.1 Limited use and disclosure

The Recipient must take all action necessary to maintain the secrecy of the Data and, without limiting the foregoing, will not:

- (a) use the Data other than for the performance of the Research Purpose;
- (b) disclose the Data to any other person other than its employees who reasonably require access to the Data in the performance of the Research Purpose; or
- (c) manufacture any product or use any process based on such Data or otherwise commercialise anything based on that Data.

2.2 Scope of obligations

In this agreement, the term Data means the information specified as such in the Details as provided by the BCTB to the Recipient but excludes information which:

- (a) is in or becomes part of the public domain other than through a breach of this agreement;
- (b) the Recipient can prove by contemporaneous written documentation was already known to it at the time of disclosure by the University; or
- (c) the Recipient acquires from a third party lawfully entitled to disclose it.

3 Monetary obligations

3.1 Delivery costs

All costs relating to the delivery of the Materials and Data to the Recipient under this agreement will be borne by the Recipient, unless otherwise specified by the BCTB.

3.2 GST gross-up

If a supply under this agreement is subject to GST and GST has not been accounted for in determining the consideration payable for the supply, the supplying party may recover from the receiving party an amount on account of GST. That amount is:

- (a) equal to the value of the supply calculated in accordance with GST law multiplied by the prevailing GST rate; and
- (b) payable at the same time as the recipient is required to pay for the related supply.

3.3 Tax invoice

The party making the supply must provide a tax invoice to the party receiving the supply if it is a taxable supply for GST purposes.

3.4 In-kind contributions

If GST is payable on an in-kind contribution by the Recipient:

- (a) the University will issue a recipient created tax invoice (“**RCTP**”) to the Recipient for the GST inclusive value of the in-kind contribution within 28 days of the supply being made;
- (b) the University warrants that it complies with the necessary legal requirements for issue of RCTIs; and
- (c) the Recipient agrees not to issue an invoice for their in-kind contributions.

4 Ownership rights

4.1 Tangible property

The Recipient acknowledges that the individual contributors of tissue to the BTCB will continue to own the Material and Data, and own Progeny and Unmodified Derivatives, and that the Recipient will hold that property on the owner’s behalf as bailee. Ownership of Modifications will be dealt with subject to clause 4.3 (Ownership of New IPRs).

4.2 Intellectual Property Rights

The Recipient acknowledges that:

- (a) the ownership of IPRs in the Material and Data remains with the BTCB;
- (b) the BTCB owns IPRs relating to Progeny and Unmodified Derivatives;
- (c) the ownership of IPRs relating to Modifications will be dealt with subject to clause 4.3(Ownership of New IPRs); and
- (d) no licence of the IPRs in the Material and Data to the Recipient beyond the rights provided by this agreement is implied by the Recipient’s use of the Material or Data.

4.3 Ownership of New IPRs

- (a) Subject to clause 4.1 all right, title and interest in any identifiable or separately registrable item of intellectual property arising from the Recipient’s use of or access to the Materials and/or Data, including any IPRs in any inventions created by the Recipient with the exception of Modifications (“**New IPRs**”), will be owned by the party/s who created or made an inventive contribution to the IPRs.
- (b) Subject to clause 4.1 all Modifications created by the Recipient will be owned jointly by the Recipient and the BTCB as tenants in common.
- (c) Each party will be entitled to use those New IPRs and Modifications for its own non-commercial research purposes with the exception of New IPRs which are (i) created solely by Recipient and not with any creative/inventive contribution from the University or the BCTB collaborating institutions (ii) do not contain any Material, Unmodified Derivatives, Progeny, and (iii) are not Modifications (“**Recipient New IPRs**”). Subject to clause 4.3(c) such Recipient New IPRs may be used at the Recipient’s sole discretion.
- (d) The Recipient will provide details of any New IPRs, Modifications and Recipient New IPRs to the BTCB Management Group within a reasonable time period from the date of creation of the New IPRs, Modifications and Recipient New IPRs and will comply with any other reasonable reporting requirements as specified in Special Term 3.
- (e) The Recipient may not use, license or assign New IPRs which are jointly owned pursuant to clause 4.3(a), Modifications, Progeny and Unmodified Derivatives for commercial purposes without written consent of the University and the BTCB Management Group. For the avoidance of doubt, this clause does not apply to Recipient New IPRs which may be used at the Recipient’s sole discretion.

4.4 Pre-existing rights

The provision of the Material and Data to Recipient will not alter or detract from any Third Party Rights in the Material and Data.

5 Publication

5.1 Publication rights

Subject to clause 5.2 (Acknowledgments), this agreement will not be interpreted as preventing or delaying publication of research findings resulting

from use of the Material, Modifications or Data by the Recipient.

5.2 Acknowledgments

The Recipient agrees to appropriately acknowledge the of the Material or Data in all publications which contain, refer to or use the Material or Data in accordance with Special Term 9 and the Recipient agrees to send the BTCB a copy of any such publications at the time of submission or publication.

6 Warranties and liability

6.1 No warranties

The Recipient acknowledges that the Material is experimental in nature and may have hazardous properties. To the extent permitted by law and subject to clause 6.3 (Statutory terms), the University and the BTCB makes no representation or warranty that the Material or Data is fit for the particular purpose for which it is required by the Recipient. The University and the BTCB expressly excludes and disclaims any warranties that;

- a) the use of the Material or Data for the Research Purpose will not infringe any third party IPRs or other rights or that;
- b) the Recipient is able to perform the Research Purpose or to use or commercialise the research results.

6.2 Implied warranties

To the extent permitted by law and subject to clause 6.3 (Statutory terms), the University and the BTCB excludes all implied terms, representations and warranties whether statutory or otherwise, relating to the subject matter of this agreement.

6.3 Statutory terms

Where any statute implies in this agreement any term, and that statute voids or prohibits provisions under a contract which exclude or modify the operation of such term, such term is deemed to be included in this agreement. However, the University's and the BTCB's liability for breach of such term will be, if permitted by law, limited (at the University's and BTCB's option) to replacement of the goods or supply of equivalent goods, or the payment of the costs of replacing the goods or of acquiring equivalent goods.

6.4 Liability limit

Subject to clause 6.3 (Statutory terms), the University's and BCTB's total liability to the Recipient for loss or damage of any kind, however caused, due to the University's or BTCB's negligence, breach of contract, breach of any law, in equity, under indemnities or otherwise, arising from or in any way related to this agreement, the Material or the Data is limited to \$2,000.

6.5 Liability for use

The Recipient assumes all liability for damage or loss which may arise from the Recipient's use, storage or disposal of the Material and Data or exploitation of Recipient New IPRs. The Recipient indemnifies the University and the BTCB for any liability, loss, costs, damages and expenses (including legal costs and expenses) incurred or suffered by the University and the BTCB collaborating institutions from any claim or demand by any other person due to or arising from the use, storage or disposal of the Material and Data by the Recipient and exploitation of the Recipient New IPRs by the Recipient or a third-party, except to the extent caused by the gross negligence or wilful misconduct of the University or the BCTB collaborating institutions.

7 Termination

7.1 Termination events

This agreement will terminate on the earliest of:

- (a) completion of the research associated with the Research Purpose; or
- (b) written notice by the University or BTCB Management Group following a breach by the Recipient of a terms of this agreement which the Recipient failed to remedy within 14 days after receiving notice requiring them to do so; or
- (c) 30 days written notice by either party without reason (subject to clause 7.3 (Request to defer termination)); or
- (d) expiration or non-renewal of ethics approval for the Research Purpose; or
- (e) the Expiry Date.

7.2 Consequences

On termination of this agreement under clause 7.1 (Termination events), the Recipient agrees to:

- (a) undertake an audit of the remaining Material and within 60 days provide the BTCB with a complete list of all Materials which remain in existence at the date of termination ("Extant Materials"); and
- (b) discontinue its use of the Extant Material and Data and either return to the BTCB or, at the option of the BTCB, destroy the Data and any Extant Material and certify that destruction to the BTCB; and
- (c) either destroy any Modifications or remain bound by the terms of clause 4 (Ownership rights) as they apply to Modifications.

7.3 Request to defer termination

In the event of termination under clause 7.1(c) (Termination events), the Recipient may request the effective date of termination be deferred for a period of up to one year to permit completion of research in progress. The BTCB may only withhold approval to defer termination on reasonable grounds, including imminent health risk, obligations to third parties or IPRs infringement.

7.4 Request to conduct further research

On Termination of this agreement under clause 7.1 (Termination events) the Recipient may only undertake further research with the Extant Materials and the Data with the written permission of the University and the BCTB Management Group, such permission will be determined in accordance with BTCB's Access Policy.

7.5 No prejudice

Termination of this agreement is without prejudice to the rights of the terminating party to obtain damages for any breach of this agreement.

7.6 Survival

Clauses 2 (Data), 4 (Ownership rights), 6 (Warranties and liability), 7.1 (Termination Events), 7.2 (Consequences) and 8 (Disputes), Special Terms survive the termination of this agreement for any reason.

8 Disputes

Any dispute relating to this agreement ("**Dispute**") must, prior to a party initiating litigation (other than for equitable or interlocutory relief), be dealt with as follows:

- (a) the affected party will notify the other with details of the Dispute ("**Dispute Notice**") and, within 7 days of receiving the Dispute Notice, the Project Officers will confer and attempt to resolve the Dispute;
- (b) if unresolved within 14 days of the Dispute Notice, the Dispute will be escalated to two executives from each party who will confer and attempt to resolve the Dispute;
- (c) if still unresolved within a further 14 days of being escalated, either party may refer the Dispute to mediation;
- (d) if the parties cannot agree on a mediator within a further 14 days, the Dispute will be referred by the parties to the President, Australian Commercial Disputes Centre, Sydney to nominate a suitably qualified mediator and the parties will accept that nomination;
- (e) the parties will cooperate to enable the mediator to mediate the Dispute within 30 days of the mediator's appointment; and

- (f) the fees of the mediator will be paid by the parties in equal proportions.

9 General

9.1 Terms and entire agreement

This agreement consists of these General Terms, the Details, the Special Terms and any annexures or schedules expressly incorporated and it constitutes the entire agreement of the parties about its subject matter and supersedes all previous agreements, understandings and negotiations on that subject matter.

9.2 Inconsistency

If there is an inconsistency between a provision of the Details, the Special Terms, any annexures or schedules expressly incorporated and these General Terms then the first-mentioned terms prevail.

9.3 No representations or warranties

The Recipient acknowledges that in entering into this agreement it has not relied on any representations or warranties about its subject matter except as expressly provided by this agreement.

9.4 Variation and waiver

A provision of this agreement or a right created under it may not be waived or varied except in writing, signed by the party or parties to be bound. A failure or delay in exercise of a right arising from a breach of this agreement does not constitute a waiver of that right.

9.5 Governing law

This agreement is governed by the law in force in New South Wales. Each party submits to the non-exclusive jurisdiction of the courts of that place.

9.6 Counterparts

This agreement may be executed in counterparts. All counterparts when taken together are to be taken to constitute one instrument.

9.7 No exclusivity

The Recipient is not acquiring the Material or the Data on an exclusive basis and this agreement will not preclude the University from providing the Material or the Data to another party.

9.8 Consideration

This agreement is entered into in consideration of the parties incurring obligations and giving rights under this agreement and for other valuable consideration.

9.9 General interpretation

Unless the contrary intention appears, in this agreement:

- (a) references to University statutes, regulations, policies, rules or code include references to those statutes, regulations, policies, rules or codes as amended, updated or replaced from time to time;
- (b) references to the singular includes the plural and vice versa;
- (c) references to person or individuals include a firm, a body corporate, a partnership, a joint venture, an unincorporated body or association, or any government agency;
- (d) the words “include” and “including” are not used as, nor are they to be interpreted as, words of limitation;
- (e) headings are for convenience only and do not affect interpretation;
- (f) reference to a party means a party to this agreement and includes the party’s executors, administrators, successors and permitted assign;
- (g) references to dollars is to Australian dollars, unless otherwise stated;
- (h) a provision of this agreement will not be construed to the disadvantage of a party merely because that party was responsible for the preparation of the agreement or the inclusion of the provision in the agreement;
- (i) if an act must be done on a specified day which is not a business day, it must be done instead on the next business day; and
- (j) where consent or approval is to be provided under the terms of this agreement, that consent or approval must not be withheld unreasonably.
- Material, for example: sub-clones of unmodified cell lines; purified or fractionated sub-sets of the Material; proteins expressed from DNA and/or RNA; DNA or RNA supplied by Provider; polyclonal and/or monoclonal antibodies secreted by a hybridoma cell lines; or sub-sets of the Material such as novel plasmids or vectors.

10 Definitions

The following words have these meanings in this agreement:

IPRs means all registered and unregistered rights in relation to present and future copyright, trade marks, designs, know-how, patents, confidential information and all other intellectual property as defined in article 2 of the Convention establishing the World Intellectual Property Organisation 1967.

Modifications means any substances created by the Recipient through use of the Material which contain or incorporate the Material and includes derivatives.

Progeny means an unmodified descendant from the Material, such as virus from virus, cell from cell, organism from organism.

Unmodified Derivatives means substances created by Recipient which constitute an unmodified functional sub-unit or an expression product of the

Schedules: (delete if not applicable)

Schedule 1 – Materials (attach complete list of materials)

Schedule 2 – Approved Research Purpose (attach proposal as approved by the BCTB Management Committee)