Royal Papworth Hospital NHS Foundation Trust

MATERIAL TRANSFER AGREEMENT

***Commercial projects***

**THIS This Material Transfer Agreement (the “Agreement”)** is entered into on the Effective Date **BETWEEN:**

1. **ROYAL PAPWORTH HOSPITAL NHS FOUNDATION TRUST**

(Acting by its RESEARCH TISSUE BANK) of Papworth Road, Cambridge Biomedical Campus, Cambridge CB2 0AY United Kingdom (“the Trust”)

1. **[INSERT FULL LEGAL NAME OF RECIPIENT INSTITUTION** (“the Recipient”)

Each of which shall be a “**Party**” and collectively the “**Parties**”

**WHEREAS** the Recipient wishes to access and utilise certain tissues (or tissue derivatives) (the “Tissues”) for the purposes of a research project specified in Clause 1.6 (the “Project”);

**WHEREAS** the term “Tissues” includes (but is not limited to) material, other than gametes or embryos, which consists of, or includes, human cells and which is considered “Relevant Material” for the purposes of the Human Tissue Act 2004 together with associated clinical data;

**WHEREAS** the Trust agrees to supply to the Recipient the Tissues and in consideration of such supply the Recipient has agreed to comply with the terms of this Agreement.

**NOW THEREFORE** the Parties hereby agree as follows:

1. **Supply of Tissues**
	1. The Trust agrees to supply the following Tissuesto the Recipient, for a period of three years (the “Term”) from the date of the final signature hereof (the “Effective Date”):

|  |
| --- |
| List of Tissues |
| *(e.g. Blood, plasma and serum samples, associated clinical data)* |

* 1. For the avoidance of doubt all associated clinical data in the Tissues supplied by the Trust to Recipient in the frame of this Agreement shall be delivered in such a format so that the Recipient does not know the identity of the donor.
	2. Risk and responsibility in the Tissues shall pass to the Recipient once it is delivered to the courier/transport as organised by the Recipient. Recipient shall have obtained either:
		1. appropriate project specific ethical approval for the use of such tissue according to a REC approved research protocol *OR*
		2. appropriate generic ethical approval for the use of such tissue according to a Trust approved research protocol and REC approved conditions (obtained via completion of the Tissue Bank Application Form) *OR*
		3. an appropriate HTA licence for the storage of such tissues.
	3. The Trust represents that all Tissues supplied under the terms of this Agreement have been obtained in compliance with all relevant UK laws and guidelines, consents and approvals.
	4. The Parties agree that the Tissues will be collected in accordance with the approved Project protocol (or other document) which may be amended from time by mutual agreement.
	5. The Tissues shall be used by the Recipient solely for the purposes of the Project, as detailed below:

|  |  |
| --- | --- |
| **Project Title:** |  |
| **Project Description** |  |
| **Names of Investigators:** | Chief Investigator: <Fill in Name>Co-Investigators: <Fill in Name> |
| **Name of any Project Collaborators outside the Recipient:** | <Fill in Name><Address if Different from above> |

1.7 Recipient will own all rights, title, and interest in and to all results arising from the Project “Results” and the Recipient will grant the Trust a non-exclusive, royalty-free, fully paid up, perpetual, irrevocable, transferable, and sublicensable right to use the Results for its own non-commercial research and teaching purposes only. The Trust agrees that it shall not publish or otherwise disclose to third parties without written permission by the Recipient (except as required by Regulatory Authority or by law) any Results until such have been published by the Recipient.

1.8 The Trust is and shall be sole owner of the Tissue-associated clinical patient data “Clinical Data”. The Trust hereby grants to the Recipient a non-exclusive, royalty-free, fully paid-up license to use the Clinical Data for the sole purpose of the Project for research and development purposes including, but not limited to, research and development of commercial products, diagnostic tools and for regulatory uses.

1.9 Upon request, the Recipient shall supply to the Trust a copy of the REC application for project specific approval and a copy of the letter of approval.

#### Obligations of the Recipient

* 1. The Recipient shall notify Tissue Bank of any defect of which the Recipient alleges that the Tissue delivered is unfit for purpose as set out in the accepted application, and which should be apparent on reasonable inspection, upon arrival of human tissue at the Recipient’s premises. Materials deemed unfit may be requested by Tissue Bank to be returned to Tissue Bank’s laboratory for examination. Couriers for such return purposes will be arranged by the Recipient.
	2. The Recipient shall not transfer or sell all or part of the Tissues or Clinical Data to a third party except as otherwise permitted by this Agreement. It shall be the responsibility of the Recipient to ensure that the investigators and collaborators referred to above, as well as any of its employees, subcontractors, agents, or representatives who are working on the Project, comply with the terms of this Agreement in all respects as though they were parties to it.
	3. The Recipient shall ensure that the Tissues including any Clinical Data are used only for the purposes of the Project and not otherwise. If the Recipient wishes to use the Tissues or any part of the Tissues and/or Clinical Data for a purpose other than the specified Project, the Recipient shall seek authorisation from the Trust in writing before using the Tissues or any part of the Tissues or Clinical Data for a purpose other than the specified Project. The Recipient shall not use such Tissues or the Clinical Data for such additional purposes without obtaining the prior written consent of the R&D Department at Royal Papworth Hospital and appropriate regulatory approvals.
	4. The Recipient shall use the Tissues in accordance with Good Laboratory Practice standards, all due skill and care, with dignity, sensitivity and respect, and all applicable laws, consents, approvals, codes of practice and regulations governing the transportation, storage, use and disposal of the Tissues.
	5. The Recipient shall comply with all reasonable instructions of the Trust concerning the treatment, storage, transport and use of the Tissues. The Recipient shall be responsible for organising and arranging the collection of the Tissues from the Trust, provide appropriately labelled containers, packaging and storage medium and arrange their safe transport to the Recipient’s premises or other location for the purposes of the Project.
	6. The Recipient shall at all times keep the Tissue safe and secure and shall use all reasonable endeavours to prevent the theft of or unauthorised use or interference with the Tissues.
	7. This Agreement may be terminated immediately by notice in writing by either Party if the other Party is:
		1. in material or continuing breach of any of its obligations under this Agreement and fails to remedy the breach (if capable of remedy) for a period of thirty (30) calendar days after written notice by the non-breaching Party; or
		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.
	8. The Recipient undertakes to keep confidential all information about the Trust and its operations which it learns by reason of this Agreement save for information which is in the public domain otherwise than by reason of a breach of this clause by the Recipient.
	9. The Recipient acknowledge and accepts that the Trust is subject to the requirements of Freedom of Information Act 2000 (FOIA) and Environmental Information Regulation 2004 (EIR). This includes associated guidance and codes of practice. The Recipient acknowledges that the Trust may be required under the FOIA and/or EIR to disclose Confidential Information without consulting or obtaining consent from the Recipient. In the event that the Trust receives a request under the FOIA and/or EIR, the Trust shall take reasonable steps to notify the Recipient to the extent permissible and reasonably practical for it to do so and the Recipient shall promptly provide all necessary assistance and cooperation necessary as requested by the Trust to allow it to comply with its obligations under the FOIA and EIR. The Recipient acknowledges that the decision on whether the exemption applies under the FOIA and/or EIR is a decision solely for the Trust.
	10. The Recipient shall reimburse to the Trust all costs and expenses incurred by the Trust for this transfer as set out in Annex A.
	11. That Royal Papworth Hospital Research Tissue Bank shall be acknowledged as the source of the Tissues in any publication or presentations resulting from work on the samples provided by the Trust. Text to be used in publication:

“Tissue /and clinical data used in the research study was obtained from the Royal Papworth Hospital Research Tissue Bank. Written consent was obtained for all tissue samplesusing Royal Papworth Hospital Research Tissue Bank’s ethical approval (East of England - Cambridge East Research Ethics Committee)”

* 1. **Disclaimer**
	2. Nothing in this Agreement shall operate so as to restrict or exclude either Party’s liability for death or personal injury caused by the negligence of that Party or its Agent(s), fraud, or any liability which cannot be so restricted or excluded in law.
	3. The Recipient acknowledges the Tissue is experimental in nature and the Trust gives no warranty or assurance of any kind to the Recipient or any third party that the Tissues are free from infection (including, without limitation, HIV, hepatitis B or tuberculosis). No warranty (statutory or otherwise) or representation is given by the Trust that the Tissues are of any particular quality or fitness for any particular purpose. It shall be the sole responsibility of the Recipient to ensure that the Tissues are of satisfactory quality, free from infection and fit for the purpose of carrying out the Projects (or any other purpose).
	4. Except to the extent prohibited by law and subject to Clause 1.4, the Trust shall not be liable for any use by the Recipient or Recipient Investigators or Project Collaborators of the Tissues transferred under this Agreement. The Recipient shall ensure that all appropriate precautions are taken by its employees and any other persons coming into contact with the Tissue. No liability is accepted by the Trust to the Recipient or any third party for any loss, claim, damage or liability, of whatsoever kind or nature, due to or arising from the use, handling, storage or disposal of the Tissues by the Recipient, except when caused by the gross negligence or wilful misconduct of the Trust. To the fullest extent permitted by law, the Recipient shall indemnify and hold harmless the Trust from any and all claims, suits and liabilities arising from any use, storage or disposal of the Tissues by the Recipient for the Project.
	5. **General**
	6. If any provision of this Agreement is found by any court, tribunal or administrative body of competent jurisdiction to be wholly or partly illegal, invalid, void, voidable, unenforceable or unreasonable, it shall to the extent of such illegality, invalidity, voidness, voidability, unenforceability or unreasonableness to be deemed severable. The remaining provisions of this Agreement and the remainder of such provision shall continue in full force and effect.
	7. Failure by the Trust in enforcing or partially enforcing any provision of this Agreement will not be construed as a waiver of any of its rights under this Agreement. Any waiver by the Trust of any breach of, or any default under, any provision of this Agreement will not be deemed a waiver of any subsequent breach or default and will in no way affect the other terms of this Agreement.
	8. The parties to this Agreement do not intend that any term of this Agreement will be enforceable by virtue of the Contracts (Right of Third Parties) Act 1999 by any person that is not a party to it.
	9. Any dispute, difference or question between the Parties to this Agreement with respect to any matter arising out of or in relation to the Agreement which cannot be resolved in negotiation between the parties hereto shall be referred to the Centre for Effective Dispute Resolution Model Mediation Procedure. The decision of the mediator shall be final and binding on both parties. Each Party shall each bear its own costs in relation to the settlement of any disputes and the Parties shall share equally the costs of any independent third party involved to assist in the resolution of the dispute unless the independent third party directs that costs be apportioned differently.
	10. This Agreement sets out the entire understanding between the parties in relation to its subject matter and supersedes all prior representations, writings, negotiations or understandings with respect thereto provided that nothing in this clause shall have effect to exclude liability of either Party for fraud or fraudulent misrepresentation.
	11. English law shall govern the formation, existence, construction, performance, validity and all aspects of this Agreement. The parties shall submit to the exclusive jurisdiction of the English courts to resolve any disputes arising in relation to this Agreement.

Signed for any on behalf of Royal Papworth Hospital NHS Foundation Trust

**Signed: Signed:**

**Name: Name:**

**Date: Date:**

Signed for any on behalf of <Recipients name and address goes here>

**Signed:**

**Name:**

**Date:**

**List of Documents Reviewed by Royal Papworth Hospital Research Tissue Bank on (*insert date of document review*):**

|  |  |  |
| --- | --- | --- |
| *Document* | *Version* | *Date* |
| *(e.g. Protocol)* |  |  |
|  |  |  |
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**ANNEX A**

**Papworth Hospital Research Tissue Bank Support Agreement.**

##  **Royal Papworth Hospital NHS Foundation Trust**

**WHEREAS** the Trust has agreed to supply to the Recipient certain tissues (or tissue derivatives) as outlined in the Agreement and in consideration of such supply the Recipient agrees to compensate the Trust in respect of this costs incurred through the collection, storage and issues of said tissues.

The Trust undertakes to provide the Tissues, with relevant anonymous clinical/pathological details the Clinical Data, for approved research projects.

The Trust warrants that all Tissues supplied under the terms of this Agreement have been obtained in compliance with all relevant UK laws and guidelines, consents and approvals.

**The handling charges in relation to the supply of tissues will be covered as follows:**

*Project specific arrangements to be entered here.*