UNIVERSITY OF BIRMINGHAM

MATERIAL TRANSFER AGREEMENT

for the supply of human tissue materials where the material is human organs, tissue or cells (other than human gametes or embryos)

FOR USE IN BIOMEDICAL RESEARCH ONLY

between

THE UNIVERSITY OF BIRMINGHAM, a charitable body registered in England under registration number RC000645, incorporated under Royal Charter and having its main administrative offices at Edgbaston, Birmingham, B15 2TT, United Kingdom (the "**University**")

and

[**INSERT FULL NAME OF RECIPIENT**], having its main administrative offices at [Insert full legal address of Recipient] (the "**Recipient**")

hereinafter referred to as "the Parties" and each of them being "a Party"

BACKGROUND

A. The Human Biomaterials Resource Centre (HBRC) is a Human Tissue Authority (HTA) licensed human sample biorepository operated by the University.

B. The HBRC operates under HTA Licence 12358 to collect and distribute samples across a wide range of research themes (NorthWest – Haydock Research Ethics Committee; Ref 25/NW/0013).

C. The Recipient, having submitted an Application (as defined below) to the HBRC, or having been named as a collaborator on an Application submitted by a researcher employed by the University, wishes to obtain Materials from the HBRC for the purpose of the Study outlined in the Application.

D. The University is willing to supply the Material to the Recipient and the Recipient is willing to receive the Material in accordance with the **non-negotiable terms and conditions** contained within this agreement (the "**Agreement**")

TERMS AND CONDITIONS

1. DEFINITIONS

1.1. In this Agreement, the following words shall have the following meanings:

"**Applicable Laws**"	means all applicable environmental, health and safety laws, and other applicable laws which means all laws, rules, regulations, codes of practice, research governance or ethical guidelines, or other requirements of any regulatory authority, that may apply to the use of the Material by the Recipient from time to time, including (but not limited to) the Human Tissue Act 2004 as subsequently amended from time to time and, where relevant, the national implementations of the same;
"**Application**"	means an application submitted by the Recipient or a researcher employed by the University and accepted by the HBRC for the supply of Materials;

"**Confidential Information**"	means any information (including, without limitation, samples, materials, drawings, specifications, photographs, designs, computer code, computer programs, software, data, formulae, processes, know-how, any technical or commercial information), reports, papers, correspondence or documents which is disclosed by or on behalf of one Party to another, or to any of such other Party's employees, directors, officers, advisors or representatives, in whatever form, (including written, oral, visual or electronic), and which is marked 'Confidential' if in tangible form, or if disclosed verbally or visually, confirmed in writing as 'Confidential' within thirty (30) days of disclosure;
"**Data Protection Laws**"	refers to the legislation, regulations, and guidelines governing the processing, storage, and protection of personal data within the United Kingdom, including but not limited to the Data Protection Act 2018 and the General Data Protection Regulation (GDPR) as implemented into UK law.
"**Effective Date**"	means the date of last signature of a Party to this Agreement;
"**Data**"	means the pseudonymised data related to the Material to be shared between the Parties as detailed under Appendix A of this Agreement;
"**Donor**"	means the person from whose body the Material (or any part thereof) has come from;
"**HBRC**"	means the University's Human Biomaterials Resource Centre;
"**HTA**"	means the Human Tissue Authority;
"**Materials**"	means all materials as described on each Application form (as detailed in Appendix A) and includes any and all documents and information provided by HBRC and not limited to human tissues, blood or body fluid (and their derivatives e.g. plasma, serum, nucleic acid, cell line, homogenate, extract etc.);
"**personal data**", "**controller**", "**processes**", "**processing**" and, "**processed**"	shall have the meanings given in the Data Protection Laws;
"**Results**"	means all ideas, results, methods and inventions created, learned, conceived, developed or reduced to practice by or on behalf of the Recipient, solely or jointly with others, in connection with the use of Study (for the avoidance of doubt, Results excludes the Material and Data);
"**Study**"	means the research project to be carried out by the Recipient described in the Application.

2. CONSENT AND ETHICAL APPROVAL

2.1. The University warrants that where required by Applicable Laws the Material has been obtained from individuals with the appropriate consent and ethical approval and the University shall be liable for any claims arising due to the breach of this warranty.

2.2. The University agrees to provide copies of the ethically approved HBRC protocol, ethical approval letter, participant information sheet(s) and template consent form(s) if reasonably requested by the Recipient.

2.3. Should an individual Donor or their next of kin rescind their consent, the University will require, and the Recipient agrees to discontinue using the appropriately identified Material and return or destroy it in accordance with the University's instructions. The University hereby grants to the Recipient a non-exclusive research licence to use the Materials for the Study only.

3. USE, TRANSFER AND STORAGE

3.1. The Recipient will hold the Material on the terms of this Agreement and solely for the purpose of the Study within the research group of the Recipient. The Recipient hereby agrees that all personnel who work with the Materials shall comply with the terms and conditions of this Agreement.

3.2. The University hereby grants to the Recipient a non-exclusive research licence to use the Materials for the Study only. The Recipient may use the Materials for solely for the purposes of the Study from the date of receipt of the Materials.

3.3. The Recipient hereby agrees to comply and procure that all personnel who work with the Material comply with the terms and conditions of this Agreement. The Recipient will not use the Materials for (a) administration to human subjects or (b) "human application" as that term is defined in the Human Tissue (Quality and Safety for Human Application) Regulations 2007 (or equivalent as may be replaced or amended from time to time), or for clinical or diagnostic purposes.

3.4. The Recipient will comply fully with all applicable environmental, health and safety laws, the Human Tissue Act 2004 and other Applicable Laws with respect to the storage and use of the Material (including, but not limited to, disposal or return).

3.5. The Recipient shall use a courier with suitable skill and experience to safely transport the Materials in accordance with all Applicable Laws. The Recipient will bear the cost of carriage and any necessary insurance.

3.6. Risk in and responsibility for the Materials will pass to the Recipient once they have left the University. If so, requested by the University, the Recipient shall provide it with written confirmation of the safe receipt of the Materials promptly after their delivery to the Recipient.

3.7. Nothing included in this Agreement shall prevent the University from being able to distribute the Materials to other entities. Use of the Materials is limited to use by the Recipient only and the Material may not be passed to any third parties other than those agreed in advance with the University.

3.8. The Recipient will ensure that the Materials are traceable at all times while in the possession of the Recipient or any authorised third party.

3.9. The Recipient agrees to obtain the prior written consent of the University if there is any proposed change to the use of the Materials as described in the Application.

4. DATA

4.1. The University grants to the Recipient for the duration of the Study a non-exclusive, personal and non-transferable licence to use the Data for the Study.

4.2. The Recipient undertakes to the University:

4.2.1. to use the Data solely for the Study;

4.2.2. to restrict access to the Data to those staff personnel comprising of the Study team detailed in the Application, and to ensure that those staff and students personnel are aware of and comply with the terms of this Agreement;

4.2.3. to keep the Data confidential and not sub-license, transfer, disclose or otherwise make available the Data in whole or part to any third party except with specific prior written consent from the University;

4.2.4. to keep the Data secure by implementing organisational and technological measures appropriate to the nature and sensitivity of the data to prevent the unauthorised or accidental access, use or disclosure of the Data;

4.2.5. to notify the University as soon as reasonably practicable after becoming aware of any unauthorised or accidental access, use or disclosure of the Data, and to co-operate with any investigation made by the University in connection with the unauthorised or accidental access, use or disclosure of the Data;

4.2.6. not attempt to re-identify any individual from the Data or communicate with any individual re-identified from the Data, nor to link or attempt to link the Data to other data or information except with specific prior written consent from the University;

4.2.7. to process the Data in accordance with all applicable Data Protection Laws.

4.3. The Data is supplied by the University in pseudonymised form without the pseudonymisation key or other means for the Recipient to re-identify individuals from the Data. The Parties anticipate that the Data is not likely to be personal data in respect of the Recipient's processing, but that this is a question of fact determined by the nature of the Data, the arrangements between the Parties, and any other means available to the Recipient (whether publicly available or otherwise) to re-identify individuals form the Data. In the event that the Data is or becomes personal data when held or processed by the Recipient, the Parties agree that they shall co-operate to determine their respective responsibilities for compliance with their obligations and duties under the Data Protection Laws.

4.4. The Parties each acknowledge and agree that they may need to process personal data relating to each Party's representatives (in their respective capacities as data controllers) where relevant in order to:

4.4.1. administer and perform their respective activities and obligations under this Agreement; and

4.4.2. compile, dispatch and manage any payments agreed under this Agreement; and

4.4.3. manage this Agreement and resolve any disputes relating to it; and

4.4.4. respond and/or raise general queries relating to this Agreement; and

4.4.5. comply with their respective regulatory obligations; and

4.4.6. each Party shall process such personal data relating to each Party's representatives for the purposes set out in this Clause in accordance with their respective privacy policies. The Parties acknowledge that they may be required to share personal data with their affiliates and other relevant parties, within or outside of the country of origin, in order to carry out the activities listed in this Clause, and in doing so each Party will ensure that the sharing and use of this Personal Data complies with applicable Data Protection Laws.

5. CONFIDENTIALITY

5.1. The Party receiving or acquiring Confidential Information (the "Receiving Party") from the other Party (the "Disclosing Party") undertakes:

5.1.1. to keep all such Confidential Information confidential, and to take reasonable steps to ensure that copies of the Confidential Information made by or on behalf of the Receiving Party are protected against theft or other unauthorised access or use;

5.1.2. not to communicate or otherwise make available any such Confidential Information to any third party except with specific prior written consent from the Disclosing Party;

5.1.3. to disclose Confidential Information only to such employees, students, directors, officers, advisors or representatives of the Receiving Party who have a specific need to receive

such Confidential Information for the Purpose, and who are aware and have accepted that the Confidential Information is, and should be treated as, of a confidential nature; and

5.1.4. not to use, or allow to be used, Confidential Information other than solely for or in relation to the Purpose, unless (and then only to the extent to which) any other use shall have been specifically authorised in writing by the Disclosing Party.

5.2. The obligations in clause 5.1 shall not apply, or shall cease to apply, to such Confidential Information as the Receiving Party can show to the reasonable satisfaction of the Disclosing Party:

5.2.1. has become public knowledge other than through any fault of the Receiving Party;

5.2.2. was already known to the Receiving Party prior to disclosure by the Disclosing Party;

5.2.3. was independently developed by the Receiving Party without recourse to or use of any Confidential Information;

5.2.4. has been received by the Receiving Party from a third party who, to the Receiving Party's reasonable knowledge, did not acquire it in confidence from the Disclosing Party, or someone owing a duty of confidence to the Disclosing Party; or

5.2.5. the Receiving Party is required to disclose by law or by a requirement of a regulatory body (including requests under freedom of information legislation) provided that the Disclosing Party is notified of such a requirement within two days of receipt by the Receiving Party and only the minimum information is disclosed in order to be able to comply with the requirement.

5.3. The obligations of confidentiality provided in this Agreement shall survive its termination or expiration and remain in effect, for a period of five (5) years after the date of expiration or termination.

6. RESULTS AND PUBLICATIONS

6.1. The Materials and Data supplied by the University to the Recipient shall at all times remain under the custodianship of the University.

6.2. The University acknowledges that the Results of the Study shall belong to the Recipient and the Recipient shall be free to utilise such Results for any purpose (except to the extent the Results incorporate or include the Material and/or Data). Any Results that incorporate the Material or Data shall not be used for any commercial purpose or gain. Notwithstanding the foregoing, if the University enters into a separate research or collaboration agreement with the Recipient regarding the use of the Material and/or Data for that specific research or collaboration, the intellectual property terms of such research or collaboration agreement shall take precedence over this clause.

6.3. If the Recipient wishes to publish the Results arising from the Study using the Materials and/or Data, the Recipient agrees that any new data and/or information arising from the use of the Materials and/or Data may be made available to other researchers via the standard HBRC application process.

6.4. The Recipient will acknowledge the University as the source of the Materials. The following acknowledgement shall be employed:

"We gratefully acknowledge the contribution to this [study/publication/presentation] made by the University of Birmingham's Human Biomaterials Resource Centre which was originally set up through Birmingham Science City – Experimental Medicine Network of Excellence Project"

6.5. The Recipient will provide the University with a copy of any publication that makes references to the University and agrees that the title of the Study may be published on the University website,

together with a lay summary of Recipient's work, the names of the institutions where such work is taking place, and at the University's discretion and if requested, contact details of the Recipient.

7. WARRANTIES AND LIABILITY

7.1. The Recipient acknowledges that the Materials may have hazardous properties, contain infectious agents or pose other health and safety risks. The University makes no representations and gives no warranties either expressed or implied in relation to the Materials: including (without limitation), the quality or fitness for a particular purpose, or freedom from infection. The University will not be liable for any use made of the Materials by the Recipient.

7.2. The University further warrants that it has not provided any information (and does not intend to provide any information) which has led or may lead to the Recipient being able to identify the person from whom the Materials came.

7.3. Except to the extent prohibited by Law, the Recipient assumes all liability for damages which may arise from its receipt, use, storage or disposal of the Materials. The University will not be liable to the Recipient for any loss, claim or demand made by the Recipient, or made against the Recipient by any other party, due to or arising from its use, storage or disposal of the Materials by the Recipient, except to the extent the law otherwise requires.

7.4. The liability of either party for any breach of this Agreement, or arising in any other way out of the subject matter of this Agreement, will not extend to loss of business or profit, or to any indirect or consequential damages or losses.

7.5. The maximum liability of the University under this Agreement shall not exceed the sums detailed in Appendix B.

8. COST RECOVERY

The Recipient shall pay to the University the cost of retrieving, processing and dispatching the Materials in accordance with the details set out in Appendix B. The University reserves the right to revise the costs set out in Appendix B to take account of any reasonable increase in operating costs (including inflation) should the Study be extended beyond the period specified in the Application for completion of the Study. The University shall give the Recipient reasonable notice of such revised costs. Recipient shall make payments within 30 days of receipt of a valid invoice from the University.

9. DURATION AND TERMINATION

9.1. This Agreement shall come into effect on the Effective Date and shall continue to be in force for the period of time specified in Appendix A for completion of the Study in the Application unless extended by mutual agreement in writing.

9.2. The University has the right to terminate this Agreement forthwith at any time by means of written notice to Recipient if the HBRC ethical approval is withdrawn.

9.3. Either Party may terminate this Agreement upon written notice on the occurrence of any of the following events:

9.3.1. the other Party enters into bankruptcy or liquidation or any other arrangement for the benefit of its creditors; or

9.3.2. the other Party is in material breach of any of its obligations hereunder and such breach is not capable of remedy; or

9.3.3. the other Party is in material breach of any of its obligations hereunder and such breach is capable of remedy but the other Party remains in breach on the expiry of twenty eight calendar days after receipt by it of written notice specifying the breach and the action reasonably required to remedy the same.

9.4. In the case of any termination, the Recipient shall immediately discontinue all use of the Materials and/or Confidential Information and, at the University's discretion, promptly return or destroy (at the Recipient's own cost) all unused Materials and/or Confidential Information and provide written confirmation that this has been completed. If requested, the Recipient must certify that it has complied in full with any such requirement of the University.

10. GENERAL TERMS

10.1. **Force majeure** - Neither Party shall have any liability under or be deemed to be in breach of this Agreement for any delays or failures in performance of this Agreement which result from circumstances beyond the reasonable control of that Party. The Party affected by such circumstances shall promptly notify the other Party in writing when such circumstances cause a delay or failure in performance and when they cease to do so. If such circumstances continue for a continuous period of more than 6 months, either Party may terminate this Agreement by written notice to the other Party.

10.2. **Amendments** - This Agreement may only be amended in writing signed by duly authorised representatives of the Parties.

10.3. **Assignment** - Neither Party may assign, delegate, sub-contract, mortgage, charge or otherwise transfer any or all of its rights and obligations under this Agreement without the prior written agreement of the other Party.

10.4. **Entire agreement** - This Agreement contains the whole agreement between the Parties and supersedes and replaces any prior written or oral agreements, representations or understandings between them. The Parties confirm that they have not entered into this Agreement on the basis of any representation that is not expressly incorporated into this Agreement. Notwithstanding the foregoing, the intellectual property terms set out in a separate research or collaboration agreement entered into pursuant to Clause 6.2 shall take precedence over any conflicting terms of this Agreement.

10.5. **Waiver** - No failure or delay by the Parties in exercising any right, power or privilege under this Agreement shall impair the same or operate as a waiver of the same nor shall any single or partial exercise of any right, power or privilege preclude any further exercise of the same or the exercise of any other right, power or privilege. The rights and remedies provided in this Agreement are cumulative and not exclusive of any rights and remedies provided by law.

10.6. **Agency, partnership etc** - This Agreement shall not constitute or imply any partnership, joint venture, agency, fiduciary relationship or other relationship between the Parties other than the contractual relationship expressly provided for in this Agreement. Neither Party shall have, nor represent that it has, any authority to make any commitments on the other Party's behalf.

10.7. **Further assurance** - Each Party to this Agreement shall at the request and expense of the other execute and do any deeds and other things reasonably necessary to carry out the provisions of this Agreement or to make it easier to enforce.

10.8. **Severance** - If any provision of this Agreement is prohibited by law or judged by a court to be unlawful, void or unenforceable, the provision shall, to the extent required, be severed from this Agreement and rendered ineffective as far as possible without modifying the remaining provisions of this Agreement and shall not in any way affect any other circumstances of or the validity or enforcement of this Agreement.

10.9. **Interpretation** - In this Agreement unless the context otherwise requires:

10.9.1. words importing any gender include every gender;

10.9.2. words importing the singular number include the plural number and vice versa;

10.9.3. words importing persons include firms, companies and corporations and vice versa;

10.9.4. references to numbered clauses and schedules are references to the relevant clause in or schedule to this Agreement;

10.9.5. reference in any schedule to this Agreement to numbered paragraphs relate to the numbered paragraphs of that schedule;

10.9.6. any obligation on any Party not to do or omit to do anything is to include an obligation not to allow that thing to be done or omitted to be done;

10.9.7. the headings to the clauses, schedules and paragraphs of this Agreement are not to affect the interpretation;

10.9.8. any reference to an enactment includes reference to that enactment as amended or replaced from time to time and to any subordinate legislation or byelaw made under that enactment; and

10.9.9. where the word 'including' is used in this Agreement, it shall be understood as meaning 'including without limitation'.

10.10. **Notices** - Any notice to be given under this Agreement shall be in writing and shall be sent by first class mail or air mail to the relevant address of the relevant Party as set out below, or such other address as that Party may from time to time notify to the other Party in accordance with this Clause 10.10. Notices sent as above shall be deemed to have been received three working days after the day of posting (in the case of inland first-class mail), or seven working days after the date of posting (in the case of air mail).

10.10.1. In the case of notices to University, send to:

Assistant Director of Operations (Clinical Research Quality)
College of Medicine and Health
University of Birmingham
Edgbaston
Birmingham B15 2TT
United Kingdom

With a copy to hbrc-tissuebank@contacts.bham.ac.uk

10.10.2. In the case of notices to the Recipient, send to:

[Please insert]

10.11. **Dispute Resolution**

10.11.1. If any dispute arises in connection with this Agreement, it shall be notified in writing by one Party to the other. An initial meeting between such senior officers each Party nominates shall be held within 30 days of receipt of notice solely in order to negotiate in good faith to resolve the matter in dispute. If the dispute cannot be settled by the nominated senior officers, a nominated senior executive of the University and the equivalent senior executive of the Recipient shall meet promptly to try and resolve the dispute.

10.11.2. If the Parties fail to settle any dispute under Clause 10.11.1 within 60 days of such initial meeting, then the parties will attempt to settle it by mediation in accordance with the Centre for Effective Dispute Resolution ("CEDR") Model Mediation Procedure. Unless otherwise agreed between the Parties, the mediator will be nominated by CEDR. To initiate the mediation a Party must give notice in writing ("ADR notice") to the other Party to the dispute requesting mediation. A copy of the request should be sent to CEDR. The mediation will not start later than 30 days after the date of the ADR notice.

10.11.3. No Party may commence any court proceedings in relation to any dispute arising out of this agreement until it has attempted to settle the dispute by mediation pursuant to

the provisions of Clauses 10.11.1 and 10.11.2 above and either mediation has terminated, or the other Party has failed to participate in the mediation, provided that the right to issue court proceedings or apply for interim injunctive relief is not prejudiced by a delay.

10.12. **Third parties** - For the purposes of the Contracts (Rights of Third Parties) Act 1999 this Agreement is not intended to, and does not, give any person who is not a party to it any right to enforce any of its provisions.

10.13. **Equality** - The Parties shall not unlawfully discriminate either directly or indirectly on such grounds as gender, race, colour, national origin, disability, sexual orientation or age within the meaning of the Equality Act 2010 and all legislation, directives and guidance relating to equality and discrimination.

10.14. **Modern slavery** - The Parties shall comply with all applicable laws, statutes, regulations and codes relating to modern slavery, including but not limited to the Modern Slavery Act 2015.

10.15. **Data Protection** - The Parties will fully comply with the provisions of the Data Protection Act 2018, the General Data Protection Regulation (EU) 2016/679 and all applicable legislation, directives and guidance relating to data protection.

10.16. **Good Conduct** - The Parties shall be entitled to cancel this Agreement immediately upon written notice if the other Party or its employees or agents are found to have made, offered, accepted or taken or agreed to make or take any gift, bribe, hospitality or consideration of any kind from any person or body as an inducement or reward for showing or forbearing to show favour or disfavour to any person or for doing or forbearing to do any action in relation to or for the purposes of offering or obtaining an advantage in relation to performance of this Agreement or where such action is in contravention of the Bribery Act 2010. The Parties warrant that they have adequate and robust policies and procedures in place in accordance with guidance issued under the Bribery Act 2010.

10.17. **Export** - The Parties shall comply with all sanctions and export control laws to which they are subject and which are applicable to any items, including but not restricted to goods, materials, biological agents, software, data, know how or any other information or assistance transferred between them. In addition, the Parties hereby agree that no applicable items furnished by a Party pursuant to this Agreement, or any product or revision thereof, that is subject to export control, shall be re-exported or otherwise used by another Party or its authorized transferees outside of that Party's principal domiciliary country, without first applying for, and obtaining, if necessary, the appropriate export licence. Each Party may terminate this Agreement immediately, without incurring any liability, if it reasonably apprehends that continuing to service this Agreement would be in breach of any applicable sanctions or export control laws.

10.18. **NSI Act** - The Parties shall comply with the notification requirements of the National Security and Investment Act 2021 ("NSI Act"), as applicable. If at any point the UK Government calls-in this Agreement for a national security assessment under the NSI Act (the "Trigger Event"), then each Party shall cooperate in a prompt and timely manner and bear their own costs and expenses incurred, except that where a Party has failed to make a mandatory notification, that Party shall bear the other Party's costs and expenses, including if the Agreement has to terminate.

If the UK Government imposes certain conditions, either Party may by giving the other Party not less than 14 days' written notice:

10.18.1. require the other Party to negotiate in good faith an amendment to this Agreement that reflects the conditions imposed by the UK Government; and

10.18.2. (b) if no such amendment is agreed and made within 45 days of such request, terminate this agreement by giving the other Party not less than 14 days' written notice.

If, following a Trigger Event, the UK Government blocks the agreement and declares it void, this agreement shall automatically terminate.

10.19. **Governing Law -** This Agreement shall be governed and construed in accordance with the laws of England and the Parties agree to the exclusive jurisdiction of England.

10.20. **Counterparts** - This Agreement may be executed in one (1) or more counterparts, each of which shall be deemed an original, but all of which together shall constitute one and the same instrument. A signed copy of this Agreement delivered by e-mailed portable document format file or other means of electronic transmission shall be deemed to have the same legal effect as delivery of an original signed copy of this Agreement.

IN WITNESS WHEREOF this Agreement is executed as follows:

for and on behalf of **THE UNIVERSITY OF BIRMINGHAM**	for and on behalf of [RECIPIENT]
Signed: _____	Signed: _____
Name: _____	Name: _____
Title: _____	Title: _____
Dated: _____	Dated: _____

APPENDIX A: MATERIALS AND STUDY DETAILS

Chief Investigator:	
Title of study:	
Study end-date	As stated in original Application documentation, and subsequent amendment/extension documentation, retained by the HBRC
Research objectives:	
Human biomaterials requested:	
Clinical data requested:	

APPENDIX B: COST RECOVERY