NHS
Blood and Transplant

NON-CLINICAL FRAMEWORK MATERIAL TRANSFER AGREEMENT

BETWEEN

NHS BLOOD AND TRANSPLANT

AND

[Insert company name]

THIS CONTRACT is made on the date of the last signature between:

(1) **NHS BLOOD AND TRANSPLANT**, a Special Health Authority established under SI 2005 No 2529 of 500 North Bristol Park, Filton, Bristol BS34 7QH, United Kingdom ("**NHSBT**"); and

(2) **[Insert company name]**, (if applicable) a company registered in England, Company No **[registration number]** **whose** registered/principal office is at **[company address]** (the "**Recipient**");

each a "**Party**" and together the "**Parties**". A Party shall include all permitted assignees of the Party in question.

WHEREAS:

A. NHSBT has Materials (as defined below) surplus to clinical requirements.

B. NHSBT wishes to supply the Recipient with Materials in accordance with this Contract.

C. The Recipient may make one or more Applications to NHSBT for the supply of Materials in accordance with the terms of this Contract and each Application together with the terms of the Contract shall constitute a separate agreement between the Parties.

1 DEFINITIONS

1.1 In this Contract, the following words shall have the following meanings:

"**Acceptance Letter**" means for each Application, the letter which confirms the Recipient's account is active and contains the customer account number;

"**Application**" means each application submitted by the Recipient and accepted in writing by NHSBT, the details of which are specified in each applicable Application Form attached as a schedule to this Contract;

"**Application Form**" means for each Application, the customer application form completed by the Recipient, providing (amongst other things) details of the Permitted Purpose, which is approved by NHSBT, found at Schedule A of this Contract;

"**Confidential Information**" means information, data and material of any nature which NHSBT or the Recipient may receive or obtain in connection with the operation of the Contract and: (i) which comprises information which relates to any Donor or patient or his or her treatment or clinical or care history; or (ii) which is designated as confidential by NHSBT or that ought reasonably to be considered as confidential (however it is conveyed or on whatever media it is stored); and/or (iii) which is a trade secret. For the avoidance of doubt, Materials IP shall be deemed as NHSBT Confidential Information;

"**Contract**" means the terms of this agreement applicable to each Application (with each Application constituting a separate agreement);

"**Cost Recovery List**" is the list of prices attached in Schedule B and updated annually as applicable to each Application;

"**Data Protection Legislation**" means all applicable data protection and privacy legislations and guidance including but not limited to Regulation (EU) 2016/679 (the "**General Data Protection Regulation**" or "**GDPR**"), the Data Protection Act 2018, the Privacy and Electronic Communications (EC Directive) Regulations 2003 and any guidance or codes of practice issued by the European Data Protection Board or Information Commissioner from time to time (all as amended, updated or re-enacted from time to time);

"**Donor**" means the person from whose body the Material (or any part thereof) has come from;

"**EIR**" means the Environment Information Regulations 2004;

"Effective Date" means the date of last signature of this Contract

"**Fraud**" means any offence under any law in respect of fraud in relation to this Contract or defrauding or attempting to defraud or conspiring to defraud the government, Parliament or any contract authority as defined in regulation 3 of the Public Agreements Regulations 2006 (SI 2006/5) (as amended);

"**FOIA**" means the Freedom of Information Act 2000 as subsequently amended or re-enacted;

"**Force Majeure**" means any cause affecting the performance of this Contract arising from or attributable to acts, events, omissions, accidents or circumstances beyond the reasonable control of a Party to perform and without limiting the generality thereof shall include the following: (i) strikes, lockout or other industrial action; civil commotion, riot, invasion, war, threat or preparation for war; or (ii) fire, explosion, storm, flood, earthquake, subsidence, epidemic or other natural physical disaster; or (iii) impossibility of the use of railways, shipping, aircraft, motor transport; or (iv) damage or destruction of NHSBT or the Recipient's premises or plant where collection, processing or storage of the Materials takes place;

"**Good Industry Practice**" means the exercise of that degree of skill, diligence, prudence, risk management, quality management and foresight which would reasonably and ordinarily be expected from a skilled and experienced company or organisation engaged in activities similar to the activities that the Recipient, its staff, representatives, agents or sub-contractors and the Permitted Third Parties will be carrying out in relation to this Contract, including in accordance with any codes of practice published by relevant trade associations;

"**Good Laboratory Practice**" means the regulations and guidelines contained within the Good Laboratory Practice Regulations 1999;

"**HT Act**" means the Human Tissue Act 2004 as subsequently amended from time to time;

"Intellectual Property" means all and any patents, copyrights, trademarks, design rights, service marks, domain names, registered designs, utility models, inventions, Know-How, database rights, unregistered trademarks and service marks, trade and business names, including rights in any get-up or trade dress, confidential formulae and any other intellectual property rights and any similar rights anywhere in the world whether registered or not, including applications and the right to apply for any such rights;

"**Know-How**" means all information not publicly known which is used or required to be used in or in connection with the Materials existing in any form (including, but not limited to, that comprised in or derived from engineering, chemical and other data, specifications, formulae, experience, drawings, manuals, component lists, instructions, designs and circuit diagrams, brochures, catalogues and other descriptions) and relating to the design, development, manufacture or production of any Materials;

"**Law**" means (i) any applicable statute or proclamation or any delegated or subordinate legislation or regulation; (ii) any applicable European Union directive, regulation, decision or law; (iii) any enforceable community right within the meaning of section 2(1) European Communities Act 1972; (iv) any applicable judgment of a relevant court of law which is a binding precedent in England and Wales; and (v) any applicable code of practice in each case as applicable in England and Wales;

"**Materials**" means all materials as described on each Application Form and includes any and all documents and information provided by NHSBT and any constructs, strains, portions, progeny and unmodified derivatives (as the case may be) obtained from or as a direct result of the use of such materials; and may include human cells and other "Relevant Material" as defined in the HT Act;

"**Materials IP**" has the meaning given to it in clause 12.2;

"**MHRA"** means UK Medicines and Healthcare products Regulatory Agency;

"**Operational Day**" means 9 am to 5 pm on a day other than a Saturday, Sunday, or public or statutory bank holiday in England;

"**Permitted Purpose**" means the purpose defined in the appropriate use section of the Application Form;

"**Permitted Third Party**" means the third party organisations named in the Application Form;

"**Prohibited Act**" means either Party: (i) offering, giving, or agreeing to give to the other Party (or any of its officers, employees or agents) any gift or consideration of any kind as an inducement or reward for doing or not doing or for having done or not having done any act in relation to the obtaining or performance of this Contract or any other agreement with the other Party, or for showing or not showing favour or disfavour to any person in relation to this Contract or any other agreement with the other Party; and (ii) in connection with this Contract, paying or agreeing to pay any commission other than a payment, particulars of which (including the terms and conditions of the agreement for its payment) have been disclosed in writing to the other Party; or (iii) committing an offence under the Bribery Act 2010;

"**REC**" means Research Ethics Committee that is recognised by the Health Research Authority;

"**Recipient IP**" has the meaning given to it in clause 12.1;

"**Schedule**" means Schedule A (Application Form), Schedule B (Cost Recovery List) and any schedule attached to this Contract;
"**Self-Certify**" means the Recipient where applicable, confirms in writing that there are no changes to the information supplied by the Recipient in the Application Form (including, but not limited to, the Permitted Purpose) to the complete satisfaction of NHSBT; and

"UKECA" means the UK Ethics Committee Authority.

1.2 INTERPRETATION

In this Contract, unless the contrary intention is expressly stated, the following rules of interpretation shall apply:

(A) Words importing the masculine gender include the feminine and the neuter, and the singular includes the plural and vice versa as the context admits or requires.

(B) The expression "person" means any individual, firm, body corporate, unincorporated association, or

partnership, government, state or agency of a state or joint venture.

(C) The index and headings of the clauses and Schedules are for convenience only and have no legal effect.

(D) References to any statute or statutory provision in the Contract shall be deemed to refer to any modification or extension or re-enactment or consolidation and all statutory instruments, thereof for the time being in force whether by statute or by directive or regulation (which is, in the case of a directive or regulation, continued to have direct application within the United Kingdom up until such legislation is replaced and superseded by English law pursuant to the United Kingdom withdrawal from the European Union).

(E) Any reference in this Contract to a clause, paragraph or Schedule is a reference to a clause, paragraph or Schedule of this Contract and references in any Schedule to paragraphs relate to the paragraphs in that Schedule.

(F) Any reference to a "day" will mean a period of 24 hours running from midnight to midnight.

(G) All covenants, agreements, undertakings, indemnities, representations and warranties by more than one person are entered into, given or made by such persons jointly and severally.

(H) Any references to "writing" or "written" includes references to any communication effected by post, or any comparable means, including email.

(I) Any obligations on a Party not to do or omit to do anything include an obligation not to allow that thing to be done or omitted by a third party.

(J) Any phrase in this Contract introduced by the term "include", "including" "in particular" or any similar expression will be construed as illustrating and will not limit the sense of the words proceeding that term.

(K) The word "indemnify" in this Contract will mean to indemnify, keep indemnified and hold harmless the indemnified party from and against all costs (including the costs of enforcement), expenses (including legal expenses), liabilities (including any tax liability), injuries, direct, indirect or consequential loss (all three of which terms include, without limitation, pure economic loss, loss of profits, loss of business, depletion of goodwill and like loss), damages, claims, demands, proceedings or legal costs (on a full indemnity basis) and judgements which the indemnified party incurs or suffers and "indemnity", "indemnities" and "indemnifies" have a corresponding meaning.

(L) All references to the Contract include (subject to all relevant approvals) a reference to the Contract as amended, supplemented, substituted, novated or assigned from time to time.

(M) Whether or not expressly stated herein, all terms and conditions within this Contract shall be applicable per Application. Each Application Form, the provisions of this Contract and the Cost Recovery List form a separate agreement between the Parties.

2 DURATION

2.1 This Contract shall come into effect on the Effective Date and unless terminated sooner pursuant to clause 13 shall remain in effect until the later of (a) ten 10 years after the Effective Date; and (b) such time as all Applications have expired or been terminated (the "Term").

2.2 For each separate Application the terms of this Contract shall come into force on the date of the Acceptance Letter issued by NHSBT and terminate on the termination date specified in the Acceptance Letter which shall be two (2) years after the date of the Acceptance Letter unless clause 2.4 or 2.5 applies.

2.3 For each separate Application, this Contract may (subject to NHSBT's approval) be extended only once for a further 2 (two) year period. NHSBT will require the Recipient to successfully Self-Certify prior to the termination date in clause 2.2. If successful, NHSBT will issue a contract extension in accordance with clause 19. Failure to successfully Self-Certify by the Recipient will mean this Contract will terminate as per clause 2.2.

2.4 Under exceptional circumstances and upon NHSBT's sole discretion, which shall be guided by internal policies, NHSBT may agree to an alternative termination date to that mentioned under clause 2.2. Such termination date shall be stipulated in the Acceptance Letter.

2.5 Where the Application requires REC or UKECA approval, subject to the Recipient providing evidence (to the complete satisfaction of NHSBT) or REC approval, this Contract shall automatically terminate four (4) years after the date of the Acceptance Letter, or where the REC or UKECA approval ceases to exist or otherwise agreed between the Parties in writing.

3 SELF-CERTIFICATION

3.1 For each Application which requires extension, the Recipient shall Self-Certify every two (2) year period, to the complete satisfaction of NHSBT that (amongst other things) the use of Materials remains the same as that set out in the Permitted Purpose. Failure to Self-Certify is a material breach of this Contract.

4 SUPPLY OF MATERIALS

4.1 Upon acceptance of this Contract, NHSBT may make authorised Materials available to the Recipient

dependent on the availability of Materials. NHSBT cannot guarantee continuity of supply. NHSBT will use all reasonable endeavours to supply the Materials but, for the avoidance of doubt, is not liable for any inability to supply.

4.2 The Recipient shall only be able to place an order for the Materials once the Recipient is issued an Acceptance Letter from NHSBT.

4.3 If the Recipient has stated in the Application Form that REC or UKECA approval has been obtained, NHSBT shall not supply Materials to the Recipient, if evidence (to the complete satisfaction of NHSBT) of REC or UKECA approval (whichever is applicable) is not provided to NHSBT.

4.4 To order the Materials, the Recipient shall place all orders in writing in a form agreed with NHSBT and shall with an appropriate representative of NHSBT confirm each order sent by electronic communication.

4.5 Each order made by the Recipient pursuant to clause 4.4 shall be deemed to be a separate order to which this Contract shall apply. A breach by NHSBT of its obligations in relation to one such order shall not itself be deemed a breach of this Contract or entitle the Recipient to terminate this Contract unless the provisions of clause 13.1 apply.

4.6 The Recipient acknowledges and agrees that, at all times, the first priority of NHSBT is to provide a sustainable supply of blood, blood components, tissues and other materials to the National Health Service ("**NHS**") for clinical and therapeutic use. In the event that: (i) NHSBT requires the Materials for use within the National Health Service; or (ii) NHSBT requires the Materials for the manufacture of Plasma Products (as defined by MHRA or other equivalent licensing authority); or (iii) NHSBT requires the Materials for internal use; or (iv) there are any other changes that either prevent NHSBT from supplying the Materials or cause NHSBT to wish to discontinue supply of the Materials; NHSBT may cease supply of the Materials in accordance with clause 13.2 and shall notify the Recipient of such termination of supply.

4.7 In the instance of specific Donor consent being modified or withdrawn after the Materials have been provided to the Recipient, NHSBT shall promptly inform the Recipient and the Recipient shall immediately cease use of the relevant Materials and return any unused Materials as instructed by NHSBT. If it is not possible to cease such use as the relevant Materials have already been used or have been destroyed the data in regard to that Material must not be used. The Recipient shall provide proof of action pursuant to this clause 4.7

4.8 For each Application, the Recipient shall not sell, gift, transfer or otherwise supply the Materials to any third party, other than a Permitted Third Party as listed in each Application Form scheduled to the back of this Contract.

4.9 Under no circumstances shall the Recipient and/or the Permitted Third Parties' export the Materials outside of Great Britain, unless explicitly agreed in writing by NHSBT.

4.10 Under no circumstances shall NHSBT have any obligation to supply the identity of, or any information that in NHSBT's reasonable opinion might lead to the identification of the Donor(s).

4.11 Under no circumstances shall the Recipient attempt to identify any Donor(s).

4.12 The Recipient is responsible for arranging and paying for delivery and collection from NHSBT of the Materials and will make prior arrangements with NHSBT for such collection. The Recipient will also ensure that at collection it places and transports the Materials within appropriate containers.

4.13 The Recipient shall ensure that the Materials are kept secure at the Recipient's laboratory or other premises under the control of the Recipient and ensure that no-one other than the Recipient's authorised employees has access to them.

4.14 By signing this Contract and each Application Form, the Recipient confirms to NHSBT that the location where the Materials are to be stored is compliant with the HT Act and any relevant guidance issued by the Department of Health and Social Care, the Human Tissue Authority or national equivalents.

4.15 In relation to the transportation, receipt, storage and disposal of the Materials, the Recipient shall ensure it complies with all applicable laws and any relevant guidance issued by the Department of Health and Social Care, the MHRA, in accordance to the Law, the HT Act or national equivalents, and all ethical guidelines relating to the use, storage, transportation and disposal of the Materials for research purposes laid down by any competent body or authority.

4.16 The Recipient shall use the Materials in accordance with Good Industry Practice, Good Laboratory Practice (where applicable) and the highest standards of skill and care and shall use the Materials only for the purpose of carrying out the Permitted Purpose.

5 CONDITIONS OF USE

5.1 The Recipient acknowledges and agrees that the Materials are supplied by NHSBT to the Recipient subject to clauses 5.2 to 5.11 and the Recipient warrants that it will comply with clauses 5.2 to 5.11.

5.2 The Recipient's, and Permitted Third Parties', use of the Materials shall comply with NHSBT policies for use of material for non-therapeutic use (NHSBT will

make a copy of the policy available to the Recipient on request).

5.3 The Recipient shall, and shall procure that the Permitted Third Parties shall, only use the Materials for the Permitted Purpose unless the Recipient has obtained the prior written consent of NHSBT to use the Materials for any other purpose. NHSBT shall respond to any requests from the Recipient for such consent within a reasonable time.

5.4 All Materials are supplied for the Permitted Purpose only and the Recipient undertakes, warrants and represents that: it shall not, and shall procure that the Permitted Third Parties does not, use the Materials howsoever (i) for transfusion or transplantation purposes or any other direct application in or on humans in any form or in the manufacture of any product for therapeutic use in humans or for use as a tissue culture medium supplement; or (ii) for DNA analysis unless this is agreed and contained within the Application Form.

5.5 The Recipient acknowledges and agrees that all of the Materials are of human origin and as such: (i) may contain inherent defects; and (ii) are defined as potentially infectious, and therefore must be treated and handled by the Recipient accordingly. Where the Recipient intends to carry out tests on the Materials for any of the following, the Recipient must notify NHSBT in advance via the Application Form: Syphilis, HBV, HIV, HCV, HEV or HTLV. Any positive results must be notified to NHSBT immediately by emailing the contact details provided by NHSBT in the Application Form.

5.6 The Recipient acknowledges and agrees that the continued generosity of unpaid Donors to NHSBT is essential to the future operation of NHSBT and to the welfare of the patients undergoing treatment in the United Kingdom generally and acknowledges the Recipient's paramount responsibility to conduct its affairs, particularly those of a medical and/or surgical nature, to the highest ethical and operational standards.

5.7 Materials supplied to the Recipient are only permitted to be used for the Permitted Purpose. Should the Permitted Purpose come to an end or should the Recipient wish to request a change to the Permitted Purpose or in the event any licences, consent, or regulatory approvals be revoked which affects any projects stated in the Application Form, the Recipient shall immediately notify NHSBT in writing and cease to use the Materials.

5.8 NHSBT shall have the right to refuse to supply the Materials to the Recipient if the Recipient fails, where reasonably requested by NHSBT to do so, to specify its use of the Materials or to provide further information regarding such use.

5.9 Should the Recipient transfer, gift or donate (i) the Materials; or (ii) any sample prepared by the Recipient containing any components derived from the Materials to a Permitted Third Party, then the Recipient will ensure that it keeps a full written audit trail of precisely what has been transferred, given as a gift or donated, including an audit trail of the Materials that form a part thereof.

5.10 NHSBT shall attach a label which clearly states, "*For Non-Clinical Use Only*" to the Materials. The Recipient shall, and shall procure that the Permitted Third Parties shall, ensure that such label remains at all times attached to the Materials in the original location that it was attached by NHSBT.

5.11 In the event that the individual donation number as marked on the Materials becomes visible the Recipient shall, and shall procure that the Permitted Third Parties shall, treat the information as confidential and not use this information in any way. The Recipient acknowledges and agrees that non-compliance with this clause 5.11 shall be deemed an irremediable material breach of the Contract for the purposes of clause 13.2 and that in such event NHSBT reserves the right to terminate the Contract with immediate effect in respect of the Application which the breach relates to.

5.12 The Recipient will ensure that its employees or others (including Permitted Third Parties) who on its behalf handle Materials are aware of the hazards and risks involved in handling Materials and of this Contract. The Recipient shall ensure that it has in place all necessary safety procedures and practices and shall ensure that its employees and others comply with all safety requirements necessary for their well-being and that of others.

5.13 The Recipient shall be deemed to have accepted that the Materials supplied by NHSBT are in good order and in all respects in accordance with this Contract unless the Recipient notifies NHSBT in writing of any discrepancy in or damage to the Materials caused prior to collection by the Recipient, within five (5) Operational Days of the collection of the Materials.

6 DISPOSAL OF THE MATERIALS

6.1 The Recipient warrants that the Materials supplied will be handled and disposed of safely in accordance with all applicable laws including the HT Act, and in accordance with applicable codes of practice and guidelines.

6.2 The Recipient shall maintain a system to ensure that the Materials are accounted for as either used or disposed of and will ensure that records of this system are kept up to date and NHSBT, in line with clause 9, is provided with copies of such records for review. This will include copies of records concerning the transfer to any Permitted Third Party.

7 PERMITTED THIRD PARTIES

7.1 Subject to clause 7.2, the Recipient shall not sell, transfer, make a gift of or donate to any third party the Material for any purpose.

7.2 The Recipient may transfer the Materials in accordance with standard industry practice to the Permitted Third Parties provided the Materials supplied are labelled "*For Non-Clinical Use Only*". The Recipient will ensure that the Permitted Third Parties will be bound by the terms and conditions of this Contract.

7.3 The Recipient acknowledges and accepts that NHSBT is obliged, in accordance with public policy and to retain the goodwill of Donors, to ensure that no third party shall achieve a profit which can be attributed solely to the onward sale of any tissue or other materials donated to NHSBT. NHSBT does not ascribe a value to the Materials and the Recipient must not similarly ascribe any value to the Materials. The price paid by the Recipient for the Materials represents the costs incurred by NHSBT in making those Materials available. Accordingly, the Recipient agrees that the contractual terms on which it transfers the Materials to the Permitted Third Parties shall not result in the Recipient charging the Permitted Third Parties any more for the Materials than the price paid to NHSBT.

7.4 The Recipient acknowledges and agrees that any additional income (whether in monetary or other form) achieved in relation to the Materials: (i) can only be achieved through the Recipient's processing, storing, handling and delivery of the Materials prior to onward transfer to the Permitted Third Parties ("**Added Value Services**"); and (ii) cannot be additional income which could reasonably be considered to be made as a consequence solely of the onward transfer of the Materials by the Recipient. The Recipient acknowledges that the only manner in which it can increase its income in relation to the onward transfer of the Materials is to increase the cost to the Permitted Third Parties of the Added Value Services.

8 PAYMENT AND FEES

8.1 The Recipient shall pay NHSBT in accordance with this clause and the Cost Recovery List, subject to annual increases as notified to the Recipient.

8.2 All amounts set forth in the Cost Recovery List shall be exclusive of VAT, taxes, fees, duties or other levies which shall be payable in addition by the Recipient.

8.3 The Recipient shall reimburse NHSBT in respect of costs, if any, incurred by NHSBT in respect of packaging and delivering the Materials to the Recipient.

8.4 The Recipient will make appropriate payment to cover reasonable administration costs and for the supply and preparation of the Materials. Payment will be made by the Recipient within thirty (30) days of the date of invoice.

8.5 NHSBT shall submit monthly invoices to the Recipient on a cost per item basis in accordance with the Cost Recovery List (unless otherwise agreed in writing by NHSBT).

8.6 The invoices shall be due and payable by the Recipient within thirty (30) days of the date of the invoice, failing which interest at a rate of 4% above the Bank of England base rate shall be payable upon the outstanding amount from the due date for payment until the date of actual payment inclusive. Any interest payable shall in place of and not in addition to any statutory interest.

8.7 Failure to pay an invoice by the Recipient (thirty) 30 days from the date of the invoice in question will be classed as a material breach for the purposes of clause 13.1 and NHSBT reserves the right to recall any Materials unused.

8.8 Risk and responsibility in the use, storage and disposal of the Materials shall pass from NHSBT to the Recipient at the time of collection of the Materials by the Recipient or its agents from NHSBT.

9 AUDIT REQUIREMENTS

9.1 Subject to any statutory requirement and except as expressly provided in this Contract, the Recipient shall keep secure and maintain for the term of this Contract and six (6) years afterwards, or such longer period as may be agreed between the Parties, full and accurate records of all matters relating to this Contract.

9.2 NHSBT shall have the right to audit (the "**Permitted Party**") the Recipient's compliance with this Contract (the "**Permitting Party**"). The Permitting Party shall permit or procure permission for the Permitted Party or its authorised representative during normal business hours having given advance written notice of no less than five (5) Operational Days, access to any premises and facilities, books, data and records reasonably required to audit the Permitted Party's compliance with its obligations under this Contract and such right of access will be exercised in such a way as to cause the minimum disruption to the operation of the Permitting Party's premises.

9.3 The Recipient shall procure for NHSBT the right to audit and inspect any Permitted Third Parties in accordance with clause 9.2.

9.4 The Recipient shall provide reasonable cooperation to NHSBT, its representatives and any regulatory body in relation to any audit, review, investigation or enquiry carried out in relation to the subject matter of this Contract.

9.5 The Recipient shall provide all reasonable information as may be reasonably requested by NHSBT to evidence the Recipient's compliance with the requirements of this Contract.

10 CONFIDENTIALITY

10.1 Each Party shall consider the other Party's Confidential Information to be confidential and shall at all times treat it as confidential. Confidential Information shall not be disclosed to any other party, whether or not that information is later available in the public domain.

10.2 Subject to clause 10.4 the Recipient shall not make (or have made on its behalf) any oral or written release or statement, information, advertisement or publicity in connection with this Contract, which uses the name, symbol or trademark of NHSBT.

10.3 Under no circumstances will the Recipient at any time publish, communicate or otherwise distribute any information relating to the Materials provided by NHSBT to any third party whether or not that information is in the public domain, or becomes public knowledge. For the avoidance of doubt, this provision shall not prevent the Recipient from publishing any research data generated from use of the Materials, subject always to the provisions of clauses 10.4 and 11.1.

10.4 Subject to clause 12.4 any publication, including patent applications, of or resulting from research carried out in connection with this Contract shall acknowledge NHSBT's contribution for the Material and carry a disclaimer as NHSBT may require or in the absence of direction from NHSBT a notice as follows: "*This report is independent research. NHS Blood and Transplant have provided material in support of the research. The views expressed in this publication are those of the author(s) and not necessarily those of NHS Blood and Transplant".*

10.5 The Recipient shall submit to NHSBT a copy of the publication which NHSBT may make available to its employees.

11. WARRANTIES

11.1 The Recipient acknowledges and agrees that any written description of the Materials enclosed with the Materials or otherwise, is given by way of identification only and that such description shall not result in the supply of the Materials to the Recipient constituting sale by description.

11.2 The Recipient warrants that an authorised person, who has the authority on behalf of the Recipient, signs this Contract.

11.3 The Recipient warrants that it shall notify NHSBT immediately in writing of any changes to the Application Form (including, but not limited to, the changes identified in clause 5.7).

11.4 The Recipient warrants that the Materials supplied will be stored, used and disposed of safely in accordance with: (i) Good Industry Practice; (ii) all applicable Law; (iii) HT Act; and (iv) in a manner which permits NHSBT to comply with its obligations under Law. The Recipient further warrants that appropriate licences and approvals necessary under this Contract are obtained, valid and active.

11.5 The Recipient acknowledges and accepts that all Materials provided by NHSBT shall be considered potentially infectious and handled with universal precaution.

11.6 NHSBT represents and warrants that at the time of supply it has the right to supply the Materials and disclose the information which is supplied to the Recipient for the Permitted Purpose and that in doing the same it complies with all applicable Laws.

11.7 NHSBT warrants that the Materials will be anonymised, and no personal data will be provided to the Recipient. The Recipient warrants it will not remove the labels NHSBT has affixed to the Materials.

11.8 Other than the warranties at clause 11.6 and 11.7, NHSBT gives no warranty whatsoever in relation to the Materials and in particular does not warrant that the Materials are fit for purpose or for any use, including the Permitted Purpose. The Recipient acknowledges and agrees that it is its responsibility to satisfy itself that the Materials are suitable for its intended use.

11.9 The Recipient acknowledge**s** and accepts replacement of Materials deemed unfit for use will be at the cost of the Recipient.

11.10 All warranties, representations or terms which would otherwise have been implied into this Contract by statute or common law or otherwise with regard to the Materials supplied hereunder are expressly excluded to the fullest extent permitted by law.

12. INTELLECTUAL PROPERTY

12.1 Any Intellectual Property generated, created or derived by the Recipient from the Materials through the Permitted Purpose shall belong to the Recipient ('**Recipient IP'**).

12.2 Any existing Intellectual Property in the Materials is owned by NHSBT ("**Materials IP**").

12.3 NHSBT shall grant to the Recipient a non-exclusive, non-transferable, fully paid-up and royalty-free licence (without the right to sub-licence) to use the Materials IP for the Recipient's academic research and teaching purposes. .

12.4 The Recipient will not without NHSBT's prior written consent publish or disclose any information relating to the Materials supplied by NHSBT to the

Recipient if to do so would result in disclosure of any Intellectual Property belonging to or used by NHSBT.

13 TERMINATION

13.1 With regards to each separate Application, (i) NHSBT may terminate this Contract if the Recipient commits a material breach of this Contract and, in the case of a breach capable of remedy, has not remedied the breach within thirty (30) days of the receipt by it of a notice identifying the breach and requiring its remedy; or (ii) either Party may terminate this Contract if the other Party becomes insolvent, or a petition of bankruptcy or any similar action under relevant bankruptcy or insolvency proceedings is filed by or against it, or a receiver is appointed with respect to any asset of the other Party or liquidation proceedings are commenced by or against it (except solvent and voluntary liquidation for reorganisation purpose).

13.2 NHSBT may additionally terminate supply of Materials immediately without liability in the following circumstances: (i) as per clause 4.5, 4.6, 5.11 or (ii) if the Recipient fails to respond to three (3) attempts of communication by NHSBT in writing without reasonable justification; or (iii) if REC or UKECA approval or any equivalent approval contained within the Application Form ceases to exist or is withdrawn.

13.3 NHSBT reserves the right to terminate this Contract immediately without liability and without cause in circumstances which could bring NHSBT into disrepute.

13.4 Upon expiry of this Contract (as stipulated in the Application Form), or notification from NHSBT of termination of supply, the Recipient will immediately discontinue use of the Materials and will, upon the direction of NHSBT, either return to NHSBT or (at the Recipient's cost) destroy all remaining Materials as agreed and in accordance with the HT Act and any relevant guidance issued by the Human Tissue Authority or national equivalents. If the Materials are destroyed or exhausted, the Recipient shall provide NHSBT with prompt written confirmation of the same.

13.5 Upon notification from NHSBT of termination of supply, the Recipient will remain liable for all costs related to Materials supplied and in the process of being supplied to the Recipient once the Recipient has agreed to take such Materials, whether or not the Recipient collects those Materials.

14 LIABILITY

14.1 Notwithstanding any other provision of the Contract, neither Party excludes or limits liability to the other Party for death or personal injury caused by its negligence, for Fraud or for fraudulent misrepresentation or any other circumstance where liability may not be limited or excluded under any applicable law.

14.2 NHSBT shall not be liable to the Recipient under this Contract for any failure to supply the Materials by reason of there not being available to NHSBT adequate quantities of the Materials of the necessary quality from appropriate Donors for onward supply to the Recipient.

14.3 Should NHSBT have any liability to the Recipient arising out of or relating to this Contract or its performance or failure to perform its obligations under this Contract, whether such claims arise in contract, tort, strict liability, statute or otherwise, NHSBT's total liability shall be limited in aggregate to the total amount paid by the Recipient to NHSBT pursuant to this Contract.

14.4 Neither Party will be liable to the other for loss of profits, business, revenue, goodwill, or anticipated savings; or consequential loss or damage whether direct or indirect and whether arising in contract, tort, negligence, breach of statutory duty or otherwise provided that this limitation shall not apply to amounts due from the Recipient to NHSBT for the provision of the Materials.

14.5 NHSBT shall be under no liability in respect of any defect arising from natural deterioration of the Materials and/or any defect arising from the Recipient's and Permitted Third Parties' wilful damage, negligence or any failure to follow any advice or recommendation from NHSBT or any failure to store and/or use the Materials in accordance with any applicable Law.

14.6 NHSBT's liability for negligence in respect of defective Materials shall, unless NHSBT's negligence results in injury, or death, be limited to replacing any defective Materials with Materials which conform to the terms of this Contract.

14.7 The Recipient shall be liable for any claims, costs, expenses, liabilities or losses which are suffered by NHSBT due to any breach by the Recipient and/or Permitted Third Parties' of this Contract or negligence or breach of statutory duty by the Recipient and/or Permitted Third Parties', except insofar as such loss, damage or injury shall have been solely caused by any negligent act or omission undertaken in strict accordance with the instructions of NHSBT.

14.8 The Recipient shall indemnify NHSBT from and against all claims and losses arising from: (i) injury to the Recipient's employees and third parties; (ii) infringement of any third party intellectual property rights

14.9 Subject only to clause 14.1, NHSBT will not be liable to the Recipient and/or Permitted Third Parties' for any costs incurred by the Recipient and/or Permitted Third Parties' as result of any delay or failure in delivery of the Materials by NHSBT.

14.10 Both Parties confirm their view that specific performance of this Contract is not an appropriate remedy for the enforcement of this Contract except in

relation to enforcement of NHSBT Intellectual Property Rights, any act of dishonesty or Fraud and any other matter expressly agreed by the Parties and recorded in this Contract to be subject to a remedy of specific performance.

14.11 The provisions of clause 14.2 and clause 14.3 will not exclude or limit NHSBT's right to claim for any of the following, which result from the Recipient's and/or Permitted Third Parties' default: (i) costs and expenses which would not otherwise have been incurred by NHSBT including, without limiting the generality of the foregoing, costs relating to the time spent by NHSBT's executives and employees in dealing with the consequences of the default; and/or (ii) expenditure or charges incurred by NHSBT which would not otherwise have been incurred or would have ceased or would not have recurred; and/or costs, expenses and charges resulting from the loss or corruption of any data owned by or under the control of NHSBT.

14.12 Each Party will at all times take all reasonable steps to minimise and mitigate any losses or other matters for which one Party is entitled to be indemnified by or bring a claim against the other under this Contract.

15. FREEDOM OF INFORMATION

15.1 Each Party acknowledges that the other Party is or may be subject to the requirements of the FOIA and the EIR and shall assist and co-operate with the other Party to enable the other Party to comply with its information disclosure requirements under such legislation.

15.2 For the purposes of this clause 15 only, the "**Requesting Party**" shall be the Party asking for assistance to meet the requirements of the FOIA and the EIR; and the "**Assisting Party**" shall be the Party offering the assistance.

15.3 The Assisting Party shall: (i) transfer any request for information which relates to this Contract to the Requesting Party as soon as practicable after receipt and in any event within five (5) Operational Days of receiving the request for information; (ii) provide the Requesting Party with a copy of all information in its possession or power which relates to this Contract, in the form that the Requesting Party requires within five (5) Operational Days (or such other period as the Requesting Party may specify) of the Requesting Party requesting that information; and (iii) provide all necessary assistance as reasonably requested by the Requesting Party to enable the Requesting Party to respond to such request for information within the time for compliance set out in section 10 of the FOIA or regulation 5 of the EIR as appropriate.

15.4 The Requesting Party shall be responsible for determining at its absolute discretion whether any information provided by the Assisting Party pursuant to clause 15.2: (i) is exempt from disclosure in accordance with the provisions of the FOIA or the EIR; or (ii) is to be disclosed in response to the relevant request for information.

15.5 In no event shall the Assisting Party respond directly to a request for information on the Requesting Party's behalf unless expressly authorised to do so by the Requesting Party.

15.6 The Assisting Party acknowledges that the Requesting Party, may be obliged under the FOIA or the EIR to disclose information relating to this Contract: (i) without consulting the Assisting Party; or (ii) following consultation with the Assisting Party and having taken its views into account, provided always that where this clause 15.5 (ii) applies, the Requesting Party shall take reasonable steps in accordance with the FOIA or the EIR, where appropriate, to give the Assisting Party advanced notice, or failing that, to draw the disclosure to the Assisting Party's attention after any such disclosure.

16. PROHIBITED ACTS

16.1 Each Party represents and warrants that it has not committed any Prohibited Act and that it has in place adequate procedures to prevent bribery and corruption, as contemplated by section 7 of the Bribery Act 2010.

16.2 If either Party or its staff (or anyone acting on its or their behalf) commits any Prohibited Act or commits any offence under the Bribery Act 2010 with or without the knowledge of the other Party in relation to this Contract or any other agreement between the Parties, the other Party will be entitled: (i) to terminate the Contract without incurring any liability therefore on written notice with immediate effect and to recover from that Party the amount of any loss resulting from the termination; and (ii) to recover from that Party the amount or value of any gift, consideration or commission concerned; and (iii) to recover from that Party any loss or expense sustained in consequence of the carrying out of the Prohibited Act or the commission of the offence under the Bribery Act 2010.

16.3 Any termination pursuant to clause 16.2 shall be without prejudice to any right or remedy that has already accrued, or subsequently accrues to the terminating Party.

16.4 The limitations of liability set out in clause 14 shall not apply to the commission of any Prohibited Act.

17. THE PREVENTION OF FRAUD

17.1 Each Party shall take all reasonable steps to prevent Fraud by a Party or by its staff. Each Party shall notify the other immediately if it has reason to suspect that any Fraud has occurred or is occurring or is likely to occur in connection with this Contract.

17.2 If either Party or its staff commits Fraud, the other Party may terminate this Contract with immediate effect and recover from the other Party, the amount of any direct loss suffered by it resulting from the termination.

18 NOTICES

18.1 Any notice required to be given by either Party under this Contract shall be in writing quoting the Effective Date (which shall be stipulated in the Acceptance Letter) and shall be delivered by hand or sent by prepaid first class recorded delivery to the authorised officer or such other person as one Party may inform the other Party in writing from time to time. Notices provided by electronic communication is acceptable under this clause 18.1.

18.2 A notice shall be treated as having been received: (i) if delivered by hand within normal business hours when so delivered or, if delivered by hand outside normal business hours, at the next start of normal business hours on the next Operational Day; or (ii) if sent by first class recorded delivery mail on a normal Operational Day, at 9.00 am on the second Operational Day subsequent to the day of posting, or, if the notice was not posted on an Operational Day, at 9.00 am on the third Operational Day subsequent to the day of posting; or (iii) the case of email, at the time that the email enters the information system of the intended recipient provided that no error message indicating failure to deliver has been received by the sender.

18.3 All written and oral communications referred to in this Contract shall be in English.

19 VARIATION

19.1 Subject to clause 19.2 below, no variation to this Contract (excluding Schedule A) shall be valid unless agreed in writing and signed by the Parties. Variation to the Application Form under Schedule A shall be valid if the Application Form is signed by the Recipient and accepted by NHSBT in writing.

19.2 NHSBT, at its sole discretion, may hold an annual review and propose any reasonable variation to the terms of the Contract and the Recipient shall not unreasonably withhold or delay its consent to such variation. In addition, the Recipient acknowledges that the availability and supply of the Materials may be affected by changes to Law and other regulatory requirements, any review by a regulatory body or licensing authority, or other factors that were not in the contemplation of the Parties on the Effective Date. The Recipient therefore acknowledges and agrees that, at any time during the Term, if any of the foregoing matters arise, NHSBT may on the provision of notice in writing to the Recipient forthwith vary the terms of the Contract without incurring any liability for such variation.

20 DISPUTES

20.1 In the event of any dispute or difference between the Parties arising in connection with this Contract, the Parties will discuss and meet as appropriate to try to resolve the dispute within five (5) Operational Days of being requested in writing by the other to do so.

20.2 If the Parties are unable to settle a dispute arising out of or in connection with this Contract in the manner set out in clause 20.1 above, the same may be referred to an agreed independent third party for resolution. In the event the Parties cannot mutually agree on the identity of an independent third party, the Parties will seek resolution by requesting the Centre for Effective Dispute Resolution (as subsequently amended) to appoint an independent third party. The decision of the independent third party shall be final and binding on both Parties in the absence of manifest error. The Parties shall each bear their own costs and expenses in relation of settlement of any disputes in terms of this clause 20 and shall share equally the costs of the independent third party.

21 GENERAL

21.1 No express or implied agency or partnership will be created upon acceptance by the Recipient of this Contract.

21.2 Neither Party shall be in breach of this Contract nor liable for delay due to a Force Majeure Event. In such circumstances, the time for performance shall be extended by a period equivalent to the period during which performance of the obligation has been delayed or failed to be performed. If the period of delay or non-performance continues for thirty (30) days', the Party not affected may terminate this Contract by giving seven (7) days' written notice to the affected Party.

21.3 No failure or delay by a Party to exercise any right or remedy provided under this Contract or by law shall constitute a waiver of that or any other right or remedy, nor shall it prevent or restrict the further exercise of that or any other right or remedy. No single or partial exercise of such right or remedy shall prevent or restrict the further exercise of that or any other right or remedy.

21.4 If any provision or part-provision of this Contract is or becomes invalid, illegal or unenforceable, it shall be deemed modified to the minimum extent necessary to make it valid, legal and enforceable. If such modification is not possible, the relevant provision or part-provision shall be deemed deleted. Any modification to or deletion of a provision or part-provision under this clause 21.4 shall not affect the validity and enforceability of the rest of this Contract.

21.5 If one Party gives notice to the other of the possibility that any provision or part-provision of this Contract is invalid, illegal or unenforceable, the Parties shall negotiate in good faith to amend such provision

so that, as amended, it is legal, valid and enforceable, and, to the greatest extent possible, achieves the intended commercial result of the original provision.

21.6 Except as otherwise expressly provided by this Contract, all remedies available to the Parties for breach of this Contract are cumulative and may be exercised concurrently or separately. The exercise of any one remedy will not be deemed an election of such remedy to the exclusion of other remedies.

21.7 Neither Party shall assign, transfer, mortgage, charge, subcontract declare a trust over or deal in any other manner with any or all of its rights and obligations under this Contract without the prior written consent of the other Party (such consent not to be unreasonably withheld or delayed).

21.8 The following clauses will survive post termination of this Contract: clause 4; 5; 6; 7; 8; 9; 10; 11; 12; 14; 15; 16; 17; 18; 20, 21 and 22.

21.9 Neither Party shall subcontract or delegate in any manner any or all of its obligations under this Contract to any third party, without the prior written consent of the other Party (such consent not to be unreasonably withheld or delayed).

21.10 Unless it expressly states otherwise, this Contract does not give rise to any rights under the Agreements (Rights of Third Parties) Act 1999 to enforce any term of this Contract.

21.11 This Contract shall be construed in accordance with English law and the Recipient agrees to submit to the exclusive jurisdiction of the English Courts.

22 ENTIRE AGREEMENT

22.1. The Materials shall be supplied to the Recipient solely in accordance with this Contract. All other contractual terms which in any way add to, vary or contradict the provisions of this Contract and upon which the Recipient may seek to rely or otherwise impose on NHSBT shall be excluded and shall not form part of this Contract (whether or not such contractual terms post-date these conditions) unless NHSBT has agreed in writing to be bound by any such terms in accordance with clause 19.

22.2. With regards to each separate Application, this Contract, together with all documents referred to in it, constitutes the entire agreement and understanding of the Parties relating to the supply of the Materials and supersedes any previous agreements between the Parties in relation to the supply of the Materials.

22.3. The Recipient acknowledges and agrees that in entering into this Contract it does not rely on, and shall have no remedy in respect of any statement, representation, warranty or understanding made or given by any person, whether orally or in writing, other than as expressly set out in this Contract as a warranty. Furthermore, the Recipient acknowledges that the only remedy available for breach of warranty shall be a contractual one under the terms of the Contract.

22.4. Should any of the terms and conditions contained within this document be inconsistent or conflict with the information contained in the Application Form or the Acceptance Letter, then the documents will take priority in the following order, (i) the terms and conditions of this Contract; (ii) the Application Form; and (iii) the Acceptance Letter.

22.5. Nothing in this clause 22 shall limit or exclude any liability for fraud or fraudulent misrepresentation.

IN WITNESS whereof the Parties have caused this Contract to be entered into by their duly authorised representatives.

	NHS Blood and Transplant		**Recipient**
Signature	_____	Signature	_____
Name	_____	Name	_____
Title	_____	Title	_____
Date	_____	Date	_____

Schedule A
Application Form

The completed and approved Application Form(s) for the Recipient is referenced here in its entirety.

Schedule B

Cost Recovery List

The applicable Cost Recovery List for the Recipient is referenced here in its entirety.