**THIS AGREEMENT** is made on the date of last signature (“**Effective Date**”)

**BETWEEN:**

1. **THE SECRETARY OF STATE FOR HEALTH AND SOCIAL CARE** acting through the **MEDICINES AND HEALTHCARE PRODUCTS REGULATORY AGENCY** whose office is at Blanche Lane, South Mimms, Potters Bar, Hertfordshire, EN6 3QG, United Kingdom (“**MHRA**”); and
2. **ORGANISATION NAME** ,whose registered address is(“**Recipient**”)

**RECITAL**

The parties intend to enter into this Agreement for the purposes of the MHRA supplying certain Materials, as have been supplied to the MHRA by the Depositor, to the Recipient on the terms contained in this Agreement.

1. AGREED TERMS
   1. This Agreement is made upon the MHRA’s general terms and conditions relating to the transfer of materials (attached to this Agreement as Schedule 1) (“**Main Terms**”) and the special terms set out in clause 2 (“**Special Terms**”).
   2. Except as provided expressly in this Agreement, terms defined in the Main Terms shall have the same meaning when used in this Agreement.
   3. The Main Terms form part of this Agreement and shall have effect as if set out in full in the body of this Agreement. Any reference to this Agreement includes the Main Terms.
   4. In the event of any conflict between the Special Terms and the Main Terms, the provisions of the Special Terms shall prevail.
2. SPECIAL TERMS
   1. The Materials shall be supplied to the Recipient solely for the research purposes and non-commercial use as set out below (“**Research**”).

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| Justification for request (please provide a description of the research you will be carrying out using the Materials. "Research use only" is not sufficient. Continue on separate sheet if necessary) |

* 1. The Recipient shall ensure that any infectious or potentially infectious materials will only be handled in appropriate containment facilities by fully trained and competent staff in accordance with the appropriate national guidelines (e.g. Protection against blood-borne infections in the workplace: HIV and hepatitis, Advisory Committee on Dangerous Pathogens, UK, published 1996 by The Stationery Office, London).
  2. The Recipient agrees that, in the event that the Recipient makes or observes any new discovery, improvement or invention relating to the Materials made by the Recipient’s use of the Materials (“**Invention**”), the Recipient shall ensure timely notification of the Depositor. The Recipient shall not make or seek to make any patent application or secure any other proprietary rights to legally protect any such Invention nor publish or present in any way any such Invention except with the prior written consent of the Depositor in order to allow the Depositor to take any steps necessary to protect its intellectual property rights.
  3. The recipient shall not use, or permit the use of by others, the Material or an Invention, or any products or processes containing, using, or directly derived from the Material or any Invention for profit-making or commercial purposes (“Commercial Use”), unless an authorised officer of the Depositor has given prior written consent to such Commercial Use. In any event, prior to any Commercial Use of Inventions, the Recipient agrees to enter into good faith negotiations with the Depositor to negotiate terms reflecting the contribution of the Materials to the Invention.
  4. The Depositor shall have the right to enforce clauses 2.3 and 2.4 of these Special Terms.
  5. Any publications or presentations of the Research will duly acknowledge the Depositor and the MHRA. Copies of such publications will be sent to the Resource Manager at the address given below:

Resource Manager, Reagent Repository

Division of Diagnostics

Medicines and Healthcare products Regulatory Agency

Blanche Lane, South Mimms

Potters Bar, Herts, EN6 3QG

United Kingdom

Or emailed to: [CFAR@nibsc.org](mailto:CFAR@nibsc.org)

**MATERIALS TO BE TRANSFERRED**

* 1. The MHRA agrees to supply the following Materials to the Recipient in consideration for the Recipient paying the MHRA’s handling fees (where applicable), the costs of shipping, insurance and other associated transfer costs to the MHRA in respect of such Materials in full without any deduction in GBP within 30 days after the date of invoice for the Materials:

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| --- | --- | --- | --- |
| **Catalogue Number** | **Description** | **Quantity** | **Cost** |
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* 1. The Recipient’s address for delivery of the Materials is as follows:

RECIPIENT NAME

ADDRESS

PHONE NUMBER

EMAIL

* 1. Time shall not be of the essence in relation to any agreed delivery date.

**IN WITNESS** whereof this Agreement has been entered into by the parties or their duly authorised representatives on the date stated at the beginning.

|  |  |  |
| --- | --- | --- |
| Signed by PRINT NAME  **POSITION**  for and on behalf of **THE SECRETARY OF STATE FOR HEALTH & SOCIAL CARE** | )  ) | .........................................................  (Authorised Signatory) |
|  |  | .........................................................  Date |
| Signed by **PRINT NAME**  **POSITION**  for and on behalf of **Recipient** | )  ) | .........................................................  (Authorised Signatory) |
|  |  | .........................................................  Date |

**Schedule 1**

**MHRA General Terms and Conditions for the Transfer of Materials**

**The Recipient’s attention is drawn in particular to the provisions of clause 8.**

1. Interpretation
   1. In this Agreement, the following definitions apply:

“**Agreement**” means the Material Transfer Agreement between MHRA and the Recipient (“**Material Transfer Agreement**”), together with these Main Terms.

“**Applicable Laws and Regulations**” means all applicable laws, statutes, regulations, international conventions and protocols (including the Nagoya Protocol), and industry codes and guidelines from time to time in force relating to the handling, storage, distribution, use and disposal of biological materials (including potentially hazardous or infectious biological materials) and, where applicable, the development of vaccines or other medicinal products or medical devices.

“**Depositor**” means a third party, or third parties, which has donated or deposited the Materials, whether or not under a written agreement, with MHRA for distribution. The Depositor is identified on the data sheet accompanying the Materials.

“**Materials**” means the materials (or any part thereof) set out in the Material Transfer Agreement and any constructs, strains, derivatives, portions or progeny obtained from or as a result of the use of the Materials for the Research.

* 1. Unless the context otherwise requires, words in the singular shall include the plural and in the plural shall include the singular.
  2. A reference to any party shall include that party’s representatives.
  3. A reference to **writing** or **written** includes fax and e-mail.
  4. Any obligation on a party not to do something includes an obligation not to allow that thing to be done.
  5. Any words following the terms **including, include, in particular, for example** or any similar expression shall be construed as illustrative and shall not limit the sense of the words, description, definition, phrase or term preceding those terms.

1. Supply of the Materials
   1. In consideration of MHRA agreeing to supply the Materials to the Recipient, the Recipient agrees to be bound by the terms of this Agreement.
2. Recipient Use of Materials
   1. The Recipient shall only use the Materials for the Research and in accordance with any instructions for use or other documentation provided by MHRA.
   2. The Recipient shall at all times have and maintain appropriate policies in place to ensure the safe and proper handling, storage, use and disposal of the Materials and to safeguard the Materials from theft or misuse
   3. The Recipient shall keep the Materials at its premises, and shall keep the Materials in a safe, clean, uncontaminated and suitable environment, use the Materials only in accordance with good laboratory practice and comply with all usual precautions in handling and disposing of materials of such nature and all applicable laws and regulations. Further, the Recipient shall comply with any additional conditions of supply specified by MHRA in writing.
   4. The Materials are intended for laboratory use only and their use is expressly subject to any pre-existing third party rights and Applicable Laws and Regulations. The Recipient shall not use the Materials for application in human subjects or animals in the human food chain, or supply the whole or any part of the Materials to any other organisation.
   5. The Recipient shall not incorporate the Materials or any part thereof, including derivatives (whether modified or not) or progeny of the Materials or any modified or any reverse engineered Materials, into any product for sale except with the express prior written consent of MHRA (which may be given by MHRA in the instructions for use or other documentation provided by MHRA).
   6. The Recipient shall not use the Materials for in-vitro diagnostics where this has been expressly prohibited in the instructions for use or other documentation provided by MHRA for the Materials or this is prohibited by the Recipient’s local laws and/or regulations.
   7. The Recipient shall ensure that all its employees and all other persons engaged in research using the Materials are aware of and comply with the terms of this Agreement and it shall at all times be liable for the failure of such persons to comply with the terms of this Agreement as though such failure were a breach by the Recipient of the terms of this Agreement.
   8. The Recipient shall upon request provide MHRA with such information as may be reasonably required by MHRA for the purposes of compliance with Applicable Laws and third party rights, to which MHRA is subject, that apply to the Materials.
3. Intellectual Property Rights
   1. MHRA is the owner or custodian of the Materials and all intellectual property rights subsisting therein shall at all times remain the property of MHRA or, where applicable, the Depositor (and the supply and transfer of the Materials is made subject to such rights). Save as expressly set out in this Agreement, no right to or licence of any patent, patent application or any other intellectual property right in the Material is granted to the Recipient.
   2. The Recipient acknowledges and agrees that certain Materials have been provided to MHRA on terms imposed by, and subject to rights of, third parties, relating to access to genetic resources and fair and equitable sharing of benefits and that the Materials are provided to the Recipient, and shall be used by the Recipient, subject to such terms and rights.
4. Warranties
   1. The Recipient acknowledges that the Materials are experimental in nature and may be hazardous, infectious or can harbour infectious agents and are supplied by MHRA on an ‘as is’ basis. MHRA makes no representation and gives no warranty or undertaking in relation to them whatsoever and excludes all implied warranties to the fullest extent permitted by law. In particular MHRA makes no representation or warranty as to title, quality or fitness for purpose of the Materials or that the supply by MHRA or the use by the Recipient of the Materials will not infringe the intellectual property rights of any third party or that the Materials have been tested, whether for the presence of pathogens or otherwise.
   2. The Recipient warrants and represents to MHRA that it has in place all necessary consents, permissions and licences required by its government or other authorities for the import, storage and use of the Materials at all times.
   3. The Recipient warrants and represents to MHRA that with respect to the Materials it has complied with, and will at all times in the future comply with, all Applicable Laws and Regulations, and that, to the extent applicable, it has obtained all necessary regulatory and ethical approvals for its proposed activities.
5. Publicity and Publication
   1. Subject to clause 6.2, in any publication making reference to the Materials, due acknowledgement shall be given of the source of the Materials (quoting the MHRA’s catalogue reference number).
   2. The Recipient shall not use the name of MHRA, the MHRA, or MHRA’s role and/or reputation as a centre of the MHRA, an OMCL, a National or a European Control Testing Laboratory, or as a World Health Organisation International Laboratory, in any publication (including publicity or promotional materials) in any way which suggests or could be construed as an endorsement of the Recipient’s products, services or research by these entities.
   3. Nothing in this Agreement shall restrict MHRA’s right to disclose the existence of a relationship between MHRA and the Recipient for the purpose of declaring potential conflict of interest to any committee or regulatory body in accordance with MHRA’s statutory duties.
   4. The Recipient agrees that MHRA may inform the Depositor, or any committee or regulatory body, of the Recipient’s identity if MHRA is required to do so.
6. Termination
   1. This Agreement shall commence on the Effective Date and terminate five (5) years thereafter, unless terminated earlier in accordance with this clause 7 (“Term”). The parties may extend the Term by agreement in writing and signed by authorised representatives of the parties.
   2. MHRA may terminate this Agreement immediately upon giving notice in writing to the Recipient:
      1. if the Depositor withdraws its consent for MHRA to continue to distribute the Materials;
      2. upon breach of this Agreement by the Recipient or the persons engaged in the Research and where such breach is capable of remedy the Recipient has failed to remedy such breach within thirty (30) days of receipt of notification from MHRA of such breach; or
      3. if the Recipient becomes insolvent, or if an order is made or a resolution is passed for the winding up of the Recipient (other than voluntarily for the purpose of solvent amalgamation or reconstruction), or if an administrator, administrative receiver or receiver is appointed in respect of the whole or any part of the Recipient's assets or business, or if the Recipient makes any composition with its creditors or takes or suffers any similar or analogous action in consequence of debt, or MHRA reasonably believes that the Recipient is about to become subject to any of the foregoing.
   3. Upon termination or expiry of this Agreement for whatever reason the Recipient shall discontinue its use of the Materials and shall, in accordance with the directions of MHRA, at its own cost and expense either return or destroy any unused parts/amounts of the Materials and the Information and certify such destruction to MHRA, unless permission to retain the Materials is specifically provided in writing by an authorised officer of MHRA.
   4. Termination or expiry of this Agreement shall not affect any of the parties’ rights and remedies that have accrued as at termination.
   5. Clauses which expressly or by implication survive termination of the Agreement shall continue in full force and effect. Termination or expiry of this Agreement shall not relieve the Recipient of its obligations under this Agreement including those set out in the Special Terms and clauses 3, 5, 6, 7 and 8 of these Main Terms.
7. Limitation of liability
   1. Except to the extent prohibited by law, MHRA shall have no liability to the Recipient whether in contract, negligence or any other tort or otherwise in relation to the supply of the Materials or the use, keeping, production or disposal of the Materials or any waste products arising from the use thereof by the Recipient or by any other person.
   2. Notwithstanding the generality of clause 8.1, MHRA expressly excludes liability for loss of data, loss of profit, business or goodwill and all other indirect or consequential loss or damage suffered or incurred by the Recipient or by any other person arising from the supply of the Materials or the use, keeping, production or disposal of the Materials.
   3. The Recipient shall defend, indemnify and hold MHRA, its officers, employees and agents harmless against any loss, claim, damage or liability including reasonable legal costs and fees (of whatsoever kind or nature) including claims relating to any injury or allegation of injury to any person, including injury resulting in death, made against MHRA which may arise as a result of the wilful act, omission or negligence or the breach of any of the terms of the Agreement by the Recipient or the persons engaged in the Research, or the use, keeping, production or disposal of the Materials or any products (including medicinal products) arising from the use thereof by the Recipient or on its behalf.
   4. MHRA does not exclude liability for death or personal injury to the extent only that the same arises as a result of the negligence of its employees, agents or authorised representatives or for any fraudulent misrepresentation made by MHRA, its employees, agents or authorised representatives in relation to the supply of the Materials or otherwise in connection with this Agreement.
8. General
   1. This Agreement constitutes the entire agreement between the parties relating to its subject matter and supersedes any previous agreement between the parties relating to such subject matter. Each party acknowledges that in entering into this Agreement it does not rely on, and shall have no remedies in respect of, any statement, representation, assurance or warranty (whether made innocently or negligently) that is not set out in this Agreement.
   2. Except as set out in this Agreement, any variation to the Agreement, including the introduction of any additional terms and conditions, shall only be binding when agreed in writing and signed by both Parties.
   3. No failure or delay by a party to exercise any right or remedy provided under the Agreement 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.
   4. If any court or competent authority finds that any provision of the Agreement (or part of any provision) is invalid, illegal or unenforceable, that provision or part-provision shall, to the extent required, be deemed to be deleted, and the validity and enforceability of the other provisions of the Agreement shall not be affected. If any invalid, unenforceable or illegal provision of the Agreement would be valid, enforceable and legal if some part of it were deleted, the provision shall apply with the minimum modification necessary to make it legal, valid and enforceable.
   5. The Recipient shall not assign, charge, encumber or otherwise deal with any of the Materials or any confidential information received from MHRA relating to the Materials or any of its rights or obligations under this Agreement.
   6. In the event of the transfer of all or a substantial part of MHRA’s activities to one or more government bodies, MHRA’s rights and obligations shall, notwithstanding any provision to the contrary in the Agreement, automatically transfer to such other government body.
   7. Except as provided elsewhere in this Agreement, a person who is not a party to the Agreement shall not have any rights under or in connection with it.
   8. The Agreement, and any dispute or claim arising out of or in connection with it or its subject matter or formation (including non-contractual disputes or claims), shall be governed by, and construed in accordance with, the law of England and Wales and the parties irrevocably agree that the courts of England and Wales shall have exclusive jurisdiction to settle any dispute or claim that arises out of or in connection with this agreement or its subject matter or formation (including non-contractual disputes or claims).