**BIOLOGICAL MATERIALS TRANSFER AGREEMENT**

**DRAFT**

**25/7/2018**

**BETWEEN**

**UNIVERSITI KEBANGSAAN MALAYSIA**

**AND**

**……………………………………………………………….**

This Biological Materials Transfer Agreement(hereinafter referred to as the “Agreement”) is made on …………... 201…

**BETWEEN**

**UNIVERSITI KEBANGSAAN MALAYSIA** (hereinafter referred to as “**UKM**”), an institution of higher learning established under the Universities and University Colleges Act 1971 and having its address at UKM, Bangi, 43600 Selangor Darul Ehsan, MALAYSIA and shall include its lawful representatives and permitted assigns; of the one Part.

**AND**

**……………………………………** (hereinafter referred to as the “**Recipient**”), a company incorporated in Malaysia under the Companies Act 1965 and having its registered address at …………………………………………………, MALAYSIA and shall include its lawful representatives and permitted assigns; of the other Part,

(UKM and the Recipient shall hereinafter be referred to singularly as “the Party” and jointly as “the Parties”).

**WHEREAS**

1. UKM is one of five (5) research universities in Malaysia with a strategic direction to be the regional leader in research and academic excellence. In taking initiatives to enhance its research and academic excellence, UKM has entered into various collaborative arrangements with other parties to enhance its research collaborations.
2. UKM owns Hospital Canselor Tuanku Muhriz and Faculty of Medicine known as UKM Medical Centre (hereinafter referred to as “**UKMMC**”) which having its address at Jalan Yaacob Latif, Bandar Tun Razak, 56000 Cheras, Kuala Lumpur, Malaysia and for the purpose of this Agreement, UKM will be represented by its **UKMMC**.
3. UKM is the owner of the biological materials as more particularly described in Schedule 1 of this Ageement (hereinafter referred to as the “Biological Materials”). For the purpose of this Agreement, the term Biological Materials shall also mean any and all constructs, progeny, derivatives, portions, divisions, mutants, metabolites, improvements and components (as the case may be) obtained from or as a result of the use of the Biological Materials described in Schedule 1 of this Agreement.
4. The Recipient wishes to acquire samples of the Biological Materials for the purpose specified in Schedule 2 of this Agreement (hereinafter referred to as the “Purpose”).
5. UKM is willing to supply to the Recipient and the Recipient has agreed to accept samples of the Biological Materials on the terms and conditions of this Agreement.

**THE PARTIES HAVE REACHED AN UNDERSTANDING** as follows; -

**ARTICLE 1**

**OBJECTIVE**

The Parties, subject to the terms of this Agreement and rules, regulations and national policies from time to time in force in each Party’s country, will endeavour to jointly develop a close-working relationship in the research entitled “**PLEASE BOLD THE TITLE OF THE STUDY”** (hereinafter referred to as the “Project”) on the basis of equality and mutual benefit.

**ARTICLE 2**

**AREAS OF COOPERATION**

2.1 Each Party will, subject to the laws, rules, regulations and national policies from time to time in force, governing the Project in their respective countries, endeavour to take necessary steps to encourage and promote co-operation as follows:

1. **Specific Aim**

This Project aims to .....................................................................

1. **Project Schedule**

The period of this Project between the Parties shall be commenced on ..............................until.......................... The Parties may extend the duration of the Agreement based on the approval of the management of the Parties through a Supplementary Agreement.

1. The Parties agree that the Project shall not interfere, change, add or omit any aspect of patient management and responsibility for the patient (if any).

2.2 This Agreement shall be read in tandem and concurrently with the Project Agreement or Clinical Trial Agreement. For avoidance of doubt, in the event of any inconsistency and/or conflict, the terms and conditions as stated in this Agreement shall at all times prevail and take precedence over the terms and conditions of the Project Agreement or Clinical Trial Agreement regarding the transfer of the Biological Materials.

**ARTICLE 3**

**SUPPLY**

* 1. UKM agrees to supply to the Recipient the Biological Materials. The Recipient acknowledges that the Biological Materials have been developed by UKM and are of considerable value, both in terms of research and in terms of their potential commercial application.

3.2 Unless the Parties agree otherwise in writing, the Recipient shall be solely responsible for payment of all costs relating to processing, storage, collection, delivery and transportation of the Biological Materials to the Recipient.

* 1. Risk of damage or loss caused to or by the Biological Materials shall pass to the Recipient upon the Biological Materials leaving the premises of UKM for delivery to the Recipient. If required by the Recipient, UKM shall obtain and maintain at the cost of the Recipient insurance coverage with a reputable insurance company in respect of such delivery and transportation and shall provide the Recipient with a copy of such insurance cover upon request.

**ARTICLE 4**

**SECURITY**

The Recipient shall at all times:

* + 1. ensure the security of the Biological Materials upon receipt by the Recipient;
		2. limit access to the Biological Materials only to those of its officers, employees, agents or representatives who reasonably require access to the Biological Materials for the Purpose; and
		3. require all persons as stated in Article 4(b) above, who have access to the Biological Materials to be equally bound by the terms of this Agreement. The Recipient shall be liable for breach of this Agreement by such persons as if the breach was a breach by the Recipient of this Agreement.

**ARTICLE 5**

**PERMITTED USE**

The Recipient shall not use, analyse or evaluate the Biological Materials for any purpose other than the Purpose stated in Schedule 2 of this Agreement without the prior written consent of UKM.

**ARTICLE 6**

**NO SUPPLY TO THIRD PARTY**

* 1. The Recipient shall not sell, supply, loan or otherwise make available any Biological Materials to any person other than those persons referred to in Article 4(b).
	2. The Recipient agrees to refer to UKM any request for the Biological Materials from any person or organisation or institution other than those persons referred to in Article 4(b).

**ARTICLE 7**

**USE OF BIOLOGICAL MATERIALS**

The Recipient shall:

* + 1. use the Biological Materials in accordance with good laboratory practice and the highest standards of skill and care; and
		2. ensure the storage and use by the Recipient of the Biological Materials comply with all relevant laws, codes of practice and ethical principles. In particular, the Recipient must not use the Biological Materials in any research or trials involving human subjects and animal subjects without UKM’s prior express consent in writing.

**ARTICLE 8**

**OWNERSHIP**

* 1. The entire right, title and interest in the Biological Materials and any intellectual property rights subsisting in them, remains at all times exclusively with UKM.
	2. Nothing in this Agreement or the use of the Biological Materials by the Recipient gives the Recipient any licence or other interest in any intellectual property rights subsisting in the Biological Materials.
	3. The Recipient shall not at any time contest or challenge UKM’s ownership of the Biological Materials or any intellectual property rights subsisting in them.

**ARTICLE 9**

**BIOLOGICAL MATERIALS MODIFICATIONS**

* 1. As a condition of receiving the Biological Materials, the Recipient agrees that all results of research and development arising from the Recipient’s use of the Biological Materials that constitute a modification to the Biological Materials or the process for making such modification (“Biological Materials Modifications”) and all intellectual property rights subsisting in such Biological Materials Modifications, shall be jointly owned by UKM and the Recipient.
	2. The Recipient shall disclose in writing to UKM full particulars of all Biological Materials Modifications immediately upon their creation.
	3. The Recipient acknowledges that it shall have no licence to use the Biological Materials Modifications or any intellectual property rights subsisting in them except as required for the Purpose.
	4. The Recipient must not file any patent or other protective application for the Biological Materials Modifications or any intellectual property rights subsisting in them without UKM’s prior written consent.
	5. If the Recipient wishes to commercially exploit any Biological Materials Modifications or any intellectual property rights subsisting in them, or otherwise deal in the Biological Materials or Biological Materials Modifications, the Recipient must first enter into an appropriate agreement with UKM.

**ARTICLE 10**

**RECIPIENT RESULTS**

All results of research and development arising from the Recipient’s use of the Biological Materials other than Biological Materials Modifications (“Recipient Results”) and all intellectual property rights subsisting in such Recipient Results, shall be jointly owned by the Recipient and UKM.

**ARTICLE 11**

**NO WARRANTY**

* 1. The Recipient acknowledges that the Biological Materials are for research purposes in nature and that UKM therefore makes no representation and gives no warranty or undertaking either express or implied, in relation to them to the maximum extent permitted by law.
	2. As examples, but without limiting the foregoing, UKM gives no express or implied warranty:
		+ 1. that it owns all necessary intellectual property and other rights in the Biological Materials, or that their use will not infringe the intellectual property or other rights of any third party; or
			2. that the Biological Materials are of merchantable or satisfactory quality or fit for any particular purpose or have particular qualities or characteristics.

**ARTICLE 12**

**NO LIABILITY**

* 1. UKM shall have no liability to the Recipient whether in contract, tort or otherwise, in relation to the supply of the Biological Materials to the Recipient or the use, possession, storage or transportation by the Recipient or any other person of the Biological Materials, or the consequences of the use of the Biological Materials, to the maximum extent permitted under applicable law.

12.2 The Recipient indemnifies and holds harmless UKM and its officers, employees and representatives from and against all Claims and Losses arising from such supply, use, possession, storage or transportation, however those Claims or Losses may arise, including without limitation to the Claims and Losses arising from:

* + - 1. injury to the Recipient's employees and third parties;
			2. infringement of third party intellectual property rights; and
			3. use of the Biological Materials within or outside the scope of this Agreement.

12.3 For the purposes of this Article 12.2, “Claims” shall mean all demands, claims, proceedings, penalties, fines and liability (whether criminal or civil, in contract, tort or otherwise) and “Losses” shall mean all losses including without limitation financial losses, damages, legal costs and other expenses of any nature whatsoever. For the avoidance of doubt, the fact that UKM has reviewed a description of the proposed analysis of how the Biological Materials are to be used does not constitute any advice from UKM nor any endorsement of that analysis.

**ARTICLE 13**

**CONFIDENTIALITY**

The Recipient shall keep all information relating to the Biological Materials, Biological Materials Modifications and any Recipient Results that disclose any information relating to the Biological Materials or the Biological Materials Modifications (including the existence of such Biological Materials, Biological Materials Modifications and such Recipient Results) confidential. To the extent deemed necessary UKM shall keep Recipient Results confidential.

**ARTICLE 14**

**PUBLICATION**

14.1 Despite Article 13, UKM agrees that the Recipient may present any Recipient Results that disclose any information relating to the Biological Materials or the Biological Materials Modifications at seminars, symposia, national or regional professional meetings, and publish such Recipient Results in journals, theses, dissertations or other publications, provided however that UKM shall have been given copies of any proposed publication or presentation at least one (1) month in advance of the submission of such proposed publication or presentation to a journal, editor or other third party. UKM shall have one (1) month after receipt of such copies, to object to such proposed presentation or proposed publication if, in UKM’s reasonable opinion, a delay of publication or presentation is necessary in order to protect the commercial interests of UKM, including the need to file any application for patents, designs or other form of intellectual property protection. In the event that UKM makes such objection, the Recipient shall refrain from making such publication or presentation until UKM has given its written consent to such publication or presentation.

* 1. UKM may present any Recipient Results at seminars, symposia, national or regional professional meetings, and publish such Recipient Results in journals, theses, dissertations or other publications, provided however that Recipient shall have been given copies of any proposed publication or presentation at least one (1) month in advance of the submission of such proposed publication or presentation to a journal, editor or other third party. Recipient shall have one (1) month after receipt of such copies, to object to such proposed presentation or proposed publication if, in Recipient’s reasonable opinion, a delay of publication or presentation is necessary in order to protect the commercial interests of Recipient, including the need to file any application for patents, designs or other form of intellectual property protection. In the event that Recipient makes such objection, UKM shall refrain from making such publication or presentation until Recipient has given its written consent to such publication or presentation.
	2. The Parties agree to appropriately acknowledge the other Party in or during any publication or presentation of any Recipient Results. The first Party shall obtain the other Party’s written approval to the nature, content and scope of such acknowledgement prior to the making of the relevant publication or presentation.
	3. For the avoidance of doubt, the Recipient may publish any Recipient Results that do not disclose any information relating to any Biological Materials or Biological Materials Modifications, at any time at its sole discretion, subject to Article 14.3.

**ARTICLE 15**

**TERMINATION**

UKM may terminate this Agreement at any time by giving seven (7) days written notice to the Recipient.

**ARTICLE 16**

**RETURN OR DESTRUCTION OF BIOLOGICAL MATERIALS**

* 1. The Recipient shall return to UKM or destroy (at the Recipient’s option and cost) the Biological Materials upon the earlier of:
		+ 1. demand by UKM;
			2. termination of this Agreement; and
			3. the date on which the Biological Materials are no longer required for the Purpose.
	2. Upon any destruction of the Biological Materials under this Article 16.1, the Recipient shall provide UKM with a certificate confirming that the Biological Materials destroyed comprised all the Biological Materials in the possession or under the control of the Recipient.

**ARTICLE 17**

**GOVERNING LAW**

Malaysian law shall apply to this Agreement, and the Malaysia courts shall have non-exclusive jurisdiction.

**ARTICLE 18**

**SURVIVAL**

Clauses 8, 9,10, 11, 12,13 and 14 shall survive termination of this Agreement.

**ARTICLE 19**

**NO ASSIGNMENT**

This Agreement is personal to the Recipient and the Recipient shall not assign or otherwise transfer any of its rights or obligations under this Agreement without the prior written consent of UKM.

**ARTICLE 20**

**NON-EXCLUSIVE**

The right of the Recipient to use the Biological Materials under this Agreement is non-exclusive.

**ARTICLE 21**

**VARIATION**

No modification or alteration of, or addition to any of the provisions of this Agreement shall be made unless made in writing and signed by all Parties.

*[the remainder of this page is intentionally been left blank]*

**IN WITNESS WHEREOF**, the Parties have caused this Agreement to be executed by their duly authorized representatives on the day and year first stated above.

|  |  |  |
| --- | --- | --- |
| For and On behalf of:**UNIVERSITI KEBANGSAAN MALAYSIA** |  | ….……………………………..………………**PROF. DR. AHMAD NAZRUN SHUID**Deputy Dean (Research and Innovation)UKM Medical Centre |
|  |  |  |
|  |  | In the presence of: -…………………………………………………………**(NAME)**Principal Investigator Department of .....................UKM Medical Centre  |

For and On behalf of:

**…………………………………………….**

………………………………………………..

 **(NAME)**

Designation

............................................

............................................

 In the presence of: -

 …………………….……………………..…

 **(NAME)**

Designation

.......................................

.......................................

**SCHEDULE 1**

**BIOLOGICAL MATERIALS**

The materials will consist of:

1.

2.

3.

4.

as part of a research project described below.**SCHEDULE 2**

**PURPOSE**

**For research use only**

(Name of the Project)

**Collaborative project between**

(Name of the Researcher)

**Background and Study Design**

(Please insert)

**Protocol**

(Please insert)