RESEARCH COLLABORATIVE AGREEMENT

This Research Collaborative Agreement (“Agreement”) is entered into by and among:

The UNIVERSITY OF THE PHILIPPINES, the national university of the Philippines, created through Act No. 1870 and operating under Republic Act No. 9500, represented herein by the Chancellor of the University of the Philippines Manila, DR. CARMENCITA D. PADILLA, with office address at the 8th Floor, RCB Building, Philippine General Hospital, Manila, hereinafter referred to as the “UP” representing the [NAME OF COLLEGE/INSTITUTION] “ABBREVIATED NAME OF THE COLLEGE/INSTITUTION”;

and

The [COMPLETE NAME OF PRIVATE INSTITUTION], a (description of the institution) operating and existing under the laws of \_\_\_\_\_\_\_\_, with office address at [complete office address], represented hereby its [title or position of representative/head who will sign the Agreement], [NAME], hereinafter referred to as the “ABBREVIATED NAME OF THE INSTITUTION”;

RECITALS:

WHEREAS, the UP is created by law to serve as a research university in various fields of expertise and specialization by conducting basic and applied research and development, and promoting research in various colleges and universities, and contributing to the dissemination and application of knowledge;

WHEREAS, [state other relevant WHEREAS clauses];

WHEREAS, collaboration in research is of mutual interest to the UNIVERSITY and the Institution;

The parties therefore agree as follows:

1. OBJECTIVES OF THE COLLABORATION
   1. (State as many objectives)
2. BASIS OF COLLABORATION
   1. The parties agree to conduct a collaborative research based upon the terms and conditions contained in this Agreement.
   2. Other agreements in relation to and subsequent to the signing of this Agreement shall be in writing, dated and signed by the parties through their duly-designated representatives and properly designated as “Amendment No. \_\_\_ (date)” or Supplementary Agreement No. \_\_\_(date)”.
   3. The following documents related to this Agreement are appended by way of Annexes and considered to be part of this Agreement:
      1. Annex “A” - (description or title of document) e.g., research protocol, budget —- list down as many related documents the parties would want to be part of the Agreement;
      2. Annex “B” etc. NOTE: If there are no additional documents, this subsection (2.3) can be deleted.
3. RESEARCH SITE/S. - The collaborative research shall be conducted in (specify site/s).
4. COLLABORATIVE RESEARCHERS - The following are the researchers involved in this Agreement:
   1. UP Researcher/s
      1. DR. \_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_ Department of \_\_\_\_\_, (Name of college or institute)
      2. Name as many researchers as applicable.
   2. (Abbreviated name of institute) Researcher/s
      1. DR. \_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_ Department of \_\_\_\_\_, (Name of college or institute)
      2. Name as many researchers as applicable.
5. DUTIES AND RESPONSIBILITIES OF UP
   1. Enumerate as many as applicable.
6. DUTIES AND RESPONSIBILITIES OF (Abbreviated name of institute)
   1. Enumerate as many as applicable.
7. FINANCIAL DISCLOSURE BY RESEARCHERS - The researchers must disclose to each party with all information on their significant financial and intellectual property interests related to the research.
8. CONFIDENTIALITY
   1. Each party shall keep in confidence all information exchanged between them in the course of the Research. The Institution shall keep in confidence especially all information related to and accrued in connection with the Research, the Results, documents, and electronic records (hereinafter “Confidential Information”). All documents and electronic records that contain Confidential Information must be stored in a manner that no third party may have access thereto.
   2. Exceptions. - The confidentiality obligation shall not, however, be applied to Confidential Information, which:
      1. Was, as evidenced, in the possession of the receiving party prior to receipt of the confidential information from the other party,
      2. Has been publicly available or has become publicly available through no act or omission by the party or its employee or a consultant or breach of this agreement,
      3. The party has received from a third party without any obligation of confidentiality and which has a right to deliver such information to the other party, or On ground Any party invoking and exception set forth above has the burden of proof with respect to the existence of such an exception.
   3. Each party shall promptly return to the other party and Confidential Information no longer needed for the purposes of this agreement or if so requested by the other party. Should any third party, e.g. Regulatory Authority demand access to Confidential Information on grounds of law, the party shall without any delay and prior to making such a disclosure notify the other party of such a demand in writing. The party may then deliver only the specified Confidential Information, which the request concerns.
9. STUDY REGISTER AND PERSONAL DATA PROTECTION
   1. A Research register will be created in connection with the Research, the controller of which will be the principal investigators and the Institution where the Research is being conducted for purposes of application of the Data Privacy Act.
   2. The Research register shall be confidential and may be accessed only by the persons involved in the Research as well as the UNIVERSITY for verification purposes. Data exchange shall be de-identified and kept private in accordance with the Data Privacy Act.
   3. The UNIVERSITY including its representatives, is obliged to keep confidential the personal data of the subjects accrued in connection with the Research.
10. DATA AND RESULTS ACCRUED IN CONNECTION WITH THE STUDY

All information, documents, reports, materials and other results accrued in connection with this Research apart from the patient records and other data collected by the Institution for its own use (hereinafter “Results”) are the property of the UNIVERSITY, the use of which the UNIVERSITY may decide independently.

1. INTELLECTUAL PROPERTY RIGHTS
   1. All copyrights, industrial rights and other intellectual property rights generated as a result of this Research or in connection thereto and which are related to the Results are the property of the UNIVERSITY.
   2. The UNIVERSITY has the exclusive right of exploitation of the aforementioned copyrights, industrial rights and other intellectual property rights.
   3. The Institution is obliged to ensure, that all inventions created in the Research or as a result of the research work related thereto, and copyrights, industrial rights and other intellectual property rights which are related to the Results shall be transferred to the UNIVERSITY regardless of whether such rights shall transfer to the Institution by virtue of law.
   4. The investigator can take part in the protection of industrial and other intellectual property rights on the request by the UNIVERSITY and on its expenses.
   5. Intellectual Property Agreements. — Institution will obtain patent and copyright agreements to effectuate the purposes of this Agreement from all individuals who perform any part of the Research.
2. PUBLICATION OF RESULTS
   1. [If applicable] The Research being a multi-center Research, no results concerning the Research may be published prior to the receipt and analysis of the Research results from all Research centers or the Research has been completed in all centers.
   2. [If applicable] The principal investigator of the entire multi-center Research based in Institution-the UNIVERSITY or the entity responsible for the publication of the Research results shall be responsible for publication of the Research results.
   3. [If applicable] Other investigators may not publish any separate publications concerning the Research prior to the publication of Research results covering all Research centers. In the event the principal investigator of the entire multi-center Research or the entity in charge of the publication decides, that the Research results of a multi-center Research shall not be published, an individual investigator may publish his/her own Research records. the UNIVERSITY shall inform the investigators of the decision not to publish the results of a multi-center Research.
   4. Any possibly patentable Results or Results, which could be protected by any other industrial rights, shall not be published prior to filing the patent applications or other industrial property protection related thereto with the appropriate authorities.
   5. Upon termination of the Research, the investigator has apart from the aforementioned restrictions concerning multi-center trials, the right to independently analyse his/her own Research results and publish them with the exception to information regarded as confidential by the UNIVERSITY. the UNIVERSITY shall obtain the manuscript of the publication for its assessment sixty (60) days prior to it being submitted for publication. Should the UNIVERSITY inform the investigator of its intention to apply for a patent relating to the facts presented in the publication, the publication shall be further postponed for a maximum period of 120 days.
3. ASSIGNMENT —The parties may not assign this agreement, any part thereof, or any right or obligation related thereto to any third party without the prior written consent of the other party.
4. AMENDMENTS — All changes and amendments to this agreement shall be agreed in writing between the parties.
5. INDEMNIFICATION —
   1. The UNIVERSITY shall indemnify and hold harmless the Institution from any and all liability of Research subjects, loss, or damage it may suffer as a result of the UNIVERSITY’S negligence or breach of contract or caused by the Research Devices and medicines, compliance with the Protocol, or use of the Results.
   2. The Institution agrees to indemnify and hold harmless the UNIVERSITY from any and all liability of Research participants, loss, or damage it may suffer as a result of the Institution’s negligence or breach of contract.
6. ENSURING CONDUCT OF THE STUDY. The Institution shall be responsible for ensuring sufficient and appropriate resources for the conduct of the Research, and that no other than legal obligations or commitments of the Institution of the Research cause unreasonable damage to or delay in conducting the Research as set forth in this agreement.
7. FORCE MAJEURE
   1. Any event occurring after signing the agreement, which a party could not reasonably have taken into account at the time of the conclusion of the agreement and which prevents or delays the affected party from fulfilling of its obligations under the agreement or makes the fulfilment thereof unreasonably difficult and which can not be overcome without unreasonable loss of time or cost, shall constitute an event of force majeure.
   2. An event of force majeure shall include: strike, war, revolt, import or export prohibition, acts of God, interruption of public traffic or distribution of energy, legal labour dispute, fire or any other reason having as severe and unusual effects beyond the control of the party.
   3. If a party would wish to invoke existence of an event of force majeure as a cause for the non-compliance with any of its obligations under the agreement or delay or exemption from liability, it shall without delay inform the other party of the delay or termination of its contractual obligation in writing.
8. RETENTION AND DESTRUCTION OF STUDY RECORDS
   1. The Institution shall store the original Research results and codes at minimum fifteen (15) years after termination of the Research. The storage of Research records is included in the compensation paid by the UNIVERSITY to the Institution for the conduct of the Research.
   2. The UNIVERSITY shall notify the Institution in good time in advance and in writing if it wants the Institution to keep the records or codes after the above-mentioned 15 years.
   3. The UNIVERSITY shall notify the Institution of the time after which the records related to the Research must no longer be stored, and reimburse the Institution all additional costs incurred due to the storage exceeding fifteen (15) years. With respect to storage of records, the instructions set forth in Sections 4.9. and 5.5 of the ICH GCP are followed.
9. TRANSPARENCY. Investigators shall declare that the UNIVERSITY has provided her/him with funding for the Research whenever she/he writes or speaks in public about a matter that is the subject of this agreement or about any other issue relating to the UNIVERSITY.
10. COMPLAINTS AND LIABILITIES
    1. A party is obliged to notify the other party immediately in writing of all errors, omissions, and deficiencies detected in the conduct of the other party based on this agreement. Thereafter, the defaulting party has a duty to correct the reported error, omission, or deficiency.
    2. A party shall be liable to compensate the other party the damages caused by its breach of contract. The parties shall not, however, be liable for any indirect or consequential damages. Except for the damages caused deliberately or by gross negligence.
11. TERM AND TERMINATION OF THE AGREEMENT
    1. This agreement shall become effective upon signing by both parties. The agreement shall continue in effect until \_\_\_\_\_\_\_\_\_\_\_\_\_\_\_ or until both parties have fulfilled their obligations set forth by this agreement.
    2. Without prejudice to the term of the agreement, a party may terminate this agreement with immediate effect, if:
       1. The other party is in material default of any of its obligations under this agreement and the breach is of significant importance to the other party,
       2. The other party fails to comply with its obligations under this agreement and has not corrected its default, omission, or deficiency within four (4) weeks after the non-defaulting party has given the defaulting party written notice thereof.
       3. The principal investigator, the Institution, or the UNIVERSITY has the right to suspend the conduct of the Research and serve notice of termination with immediate effect due to any cause relating to the safety of the participants or any ethical reason.
       4. In the event a complaint based on the Research has not led to correction of an error or deficiency, the UNIVERSITY shall in addition have the right without separate obligation of compensation or refund to suspend the Research and terminate immediately in writing this agreement in the following circumstances:
          1. If a favourable opinion of the Ethics Committee is not obtained,
          2. If no subjects have been recruited within \_\_\_\_\_months followed by the initial visit of the UNIVERSITY,
          3. If the Principal Investigator has enrolled Research participants, who do not fulfill the criteria set for the subjects as defined by the Protocol,
          4. If the Principal Investigator does not follow the Protocol,
          5. If the Principal Investigator fails to comply with the 2017 National Ethical Guidelines for Health and Health-related Research.
          6. If the Principal Investigator gives notice or is given notice by the unit conducting the Research or otherwise ceases to work for the Research as defined by this agreement, and the parties fail to reach mutual understanding on the new principal investigator, or
          7. If the UNIVERSITY decides to terminate the Research for instance for scientific, ethical, or administrative reasons.

Provided that when the UNIVERSITY serves notice of termination due to any cause referred to in the preceding paragraph, the UNIVERSITY shall be oblige to compensate the Institution all necessary, irrevocable, documented, and direct costs incurred by the suspension of the Research due to the conduct of the Research.

1. SURVIVAL OF PROVISIONS. —The terms and conditions and responsibilities relating to the rights of the UNIVERSITY and the authorities, confidentiality of information, the Research register and personal data protection, data and records accrued as a result of the Research, intellectual property rights, publication of results, archiving and destroying of the Research records and governing law and dispute resolution shall survive termination or cancellation of this agreement.
2. GOVERNING LAW. This agreement shall be governed by the laws of the Republic of the Philippines as well as international guidelines relating to good clinical practices.
3. DISPUTE RESOLUTION AND FORUM
   1. In case of disputes, claims and controversies arising from the interpretation and application of this Agreement the parties agree to freely and voluntarily submit themselves to consultation and negotiation to amicably settle the dispute;
   2. Should the parties fail to reach an amicable settlement of their dispute, the same shall be submitted to arbitration, in accordance with Republic Act No. 9285 or the ADR Law of 2004.
   3. However, should the dispute between the Parties reach the courts of law, the parties agree that the competent courts of the City of Manila shall have exclusive jurisdiction over the same.”
4. PUBLICITY
   1. Neither party will identify the other in any promotional advertising or other promotional materials to be disseminated to the public or use the name of any faculty member, employee, or student or any trademark, service mark, trade name, or symbol of the other.
   2. Notwithstanding anything to the contrary, the UNIVERSITY agrees to allow publicly registered information about the Research to appear on Institution’s Clinical Trials Directory website.
5. NOTICES
   1. *Form of Notice*. All notices, requests, claims, demands, and other communications between the parties shall be in writing.
   2. *Method of Notice*. All notices shall be given (i) by delivery in person (ii) by a nationally recognized next day courier services, (iii) by first class, registered or certified mail, postage prepaid; or (iv) by email.
   3. *Receipt of Notice*. All notices shall be effective:
      1. upon receipt by the party to which notice is given,
      2. on the day the mail is returned to sender because the addressee no longer resides at the given address in this contract without notifying the other party of the new address, or
      3. after two (2) failed attempts to personally deliver the notices, requests, claims, demands and other communications, the party delivering the notice may leave the notice, request, claim, demand or other communications to a person of legal age residing or working in the address specified in No. 5 of Article XVII or to the supervisor of the construction work in the site;
      4. on the date of receipt of the email.
   4. *Refusal of Delivery*. Rejection or other refusal to accept or the inability to deliver because of change of address where the other party was not notified thereof shall be deemed to be receipt of the notice as of the date of such rejection, refusal or inability to deliver.
   5. *Party to notify*. All notices, requests, claims, demands and other communications shall only be valid, effective and binding if received by the following offices in the addresses indicated below:

For the UNIVERSITY:

Office of the Chancellor

8th Floor, Right Central Block Building

Philippine General Hospital

Taft Avenue, Ermita, Manila 1000

Email: [oc@upm.edu.ph](mailto:ovca@upm.edu.ph)

For Institution:

Office of the Director

Name of hospital: \_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_

Address: \_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_

Email: \_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_

1. MISCELLANEOUS
   1. Divisibility. If any provision of this Agreement becomes or is declared illegal, invalid, or unenforceable, such provision will be divisible from this Agreement and will be deemed to be deleted from this Agreement. If such deletion substantially alters the basis of this Agreement, the parties will negotiate in good faith to amend the provisions of this Agreement to give effect to the original intent of the parties.
   2. Independent Contractors. Institution and UNIVERSITY are independent contractors and neither is an agent, joint venturer, or partner of the other.
   3. Entire Agreement. —This agreement, including its Appendices, represents the entire understanding between the parties with respect to the conduct of the Research as described in Section 2 and supersedes all prior oral or written agreements between the parties related thereto.
   4. Non-waiver. - The failure of any party to enforce any term or provision hereof shall not be construed to be a waiver of such term or provision and shall in no way affect the right of such party thereafter to enforce such term or provision or any other term or provision thereof.
   5. Counterparts. This Agreement may be executed in multiple counterparts, each of which will be deemed an original, but all of which will constitute one and the same Agreement, and the signature pages from any counterpart may be appended to any other counterpart to assemble fully executed counterparts. Counterparts of this Agreement also may be exchanged via electronic PDF copy, and an electronic PDF copy of any party’s signature will be deemed to be an original signature for all purposes.

IN WITNESS WHEREOF, these duly authorized representatives of the parties hereby execute this Agreement, including all the terms and conditions which follow this \_\_\_\_\_\_\_\_\_\_\_\_\_\_ in the City of Manila, Philippines.

UNIVERSITY OF THE PHILIPPINES [NAME OF INSTITUTION/HOSPITAL]

by: by:

CARMENCITA D. PADILLA, MD,MAHPS [NAME OF DIRECTOR]

Chancellor, UP Manila Director

PRINCIPAL INVESTIGATOR/S:

DR. \_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_, MD

Department of \_\_\_\_\_, [Name of Hospital]

DR. \_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_, MD

Department of \_\_\_\_\_, [Name of Hospital]

SIGNED IN THE PRESENCE OF:

EVA MARIA CUTIONGCO-DE LA PAZ, MD \_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_

Vice Chancellor for Research and Position

Executive Director, National Institutes of Health

\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_

Position

ACKNOWLEDGMENT

REPUBLIC OF THE PHILIPPINES)

City of Manila ) S.S.

BEFORE ME, a Notary Public for and in City of Manila this \_\_\_th day of \_\_\_\_\_\_\_\_\_\_\_\_ 2018, personally appeared:

Name ID No. Issuing Office

CARMENCITA D. PADILLA \_\_\_\_\_\_\_\_\_\_\_\_\_ \_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_

\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_ \_\_\_\_\_\_\_\_\_\_\_\_\_ \_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_

Known to me and has been identified by me based on competent proof of identity to be the same persons who executed the foregoing instrument, and they acknowledged to me that the same is their free and voluntary act and deed as well the entities they represent. This instrument consists of eleven (11) pages including this page on which this acknowledgement is written, signed by the parties hereto together with their two instrumental witnesses on each and every page hereof.

IN WITNESS WHEREOF, I have hereunto affixed my signature and notarial seal this \_\_\_\_day of \_\_\_\_\_\_\_\_\_\_\_ 2018.

Doc. No. \_\_\_\_\_;

Page No. \_\_\_\_\_;

Book No. \_\_\_\_\_;

Series of 2018