

MEMORANDUM OF AGREEMENT

KNOW ALL MEN BY THESE PRESENTS:

This Memorandum of Agreement, entered into this 2nd day of November 2017 in _____, Philippines, by and between:

The **UNIVERSITY OF THE PHILIPPINES COLLEGE OF MEDICINE**, under the **University of the Philippines, Manila**, with office address at the 1/F Calderon Hall, College of Medicine, University of the Philippine, 547 Pedro Gil Street, Barangay 669 Zone 072, Ermita, Manila 1000, herein represented by the Dean, Dr. Agnes D. Mejia, hereinafter referred to as the "**UPCM**";

- and -

VERMILLION, INC., a corporation duly formed and organized in accordance with the laws of the U.S.A., with office/business address at 12117 Bee Caves Road, Building III, Suite 100, Austin, TX 78738, represented herein by its position of officer, hereinafter referred to as "SPONSOR"

WITNESSETH: That -

WHEREAS, the UPCM, through the Department of Physiology, as main PROPONENT, agrees to implement the study entitled *Prediction of ovarian cancer using a multivariate assay: a randomized controlled trial to improve diagnostic strategies in Filipino women*, herein referred to as the "STUDY";

WHEREAS, a total of 380 subjects will be recruited and informed consent obtained, each patient will undergo a physical examination and interview prior to standard ultrasonographic and Doppler evaluation. Ultrasonographic classification of the mass will be performed using the IOTA LR2 classification followed by OVERA blood sampling. Benign cases shall be randomized into either of two groups: disclosure or non-disclosure of OVERA results. For malignant cases and those in the benign disclosure group, OVERA testing results shall be given to consultants prior to treatment planning. All management decisions shall be documented per case. All surgery and histopathologic analysis shall be performed at the Philippine General Hospital. Data encoding, processing and analysis shall be done at the Department of Physiology, College of Medicine, University of the Philippines, Manila which is the official headquarters of the study. Management up to 1 year after the first OVERA test was performed shall be documented. A 6th and 12th month interval ultrasound shall be performed for all participants while repeat OVERA testing during this period shall be as follows: a) all patients diagnosed with cancer have 6th and 12th month interval follow up Overa testing; b) all patients who still have an adnexal mass because non-surgical treatment was chosen shall get repeat Overa testing done at 6th and 12th month intervals to help reevaluate cancer risk; and c) all patients who had surgery and a benign adnexal mass was removed will not undergo repeat Overa testing unless a new adnexal mass develops within the one year monitoring period.

WHEREAS, the SPONSOR, after thorough evaluation of the merit of the proposal, agrees to provide funding assistance to the STUDY;

WHEREAS, the SPONSOR is willing and has the financial capacity to undertake the STUDY;

WHEREAS, the UPCM, through the University of the Philippines Medical Alumni Fund, Inc. (UPMAFI) has staff who can manage the funds for the STUDY;

WHEREAS, the PRINCIPAL INVESTIGATOR (PI) is Clarissa Lim Velayo, MD, PhD, Associate Professor of the Department of Physiology, UPCM;

WHEREAS, the PI possess the qualifications and experience needed to undertake the STUDY entitled *Prediction of ovarian cancer using a multivariate assay: a randomized controlled trial to improve diagnostic strategies in Filipino women*;

NOW, THEREFORE, for and in consideration of the above premises, the parties hereby agree on the following terms and conditions:

I. OBJECTIVES OF THE STUDY

The STUDY aims to evaluate a multiplex biochemical assay for malignancy risk calculation of ovarian cancer, the OVERA test, in a Philippine tertiary hospital by its comparison with (1) clinical (2) ultrasound, (3) surgical, and (4) histopathologic findings for the development of a cost-utility analysis and local guidelines for use, specifically:

1. To evaluate patients with adnexal masses prior to management using a combined initial assessment which includes the patient's clinical profile, ultrasound findings and multiplex biochemical assay results.
 - a. To assess the clinical validity of a multiplex biochemical assay in a Filipino population.
 - b. To ascertain the clinical utility of testing with a multiplex biochemical assay to determine the need for certain considerations (e.g. gynecologic-oncology specialist intervention prior to surgery, laparoscopy or laparotomy, frozen section) based on the reported probability of malignancy of the ORS.
2. To correlate the surgical findings of these adnexal masses with the results of the combined initial assessment.
 - a. To compare the outcome of histopathologic findings with clinical profiles, ultrasound findings and biomarker values.
 - b. To correlate the combined initial assessment and surgical findings across ovarian, cancer subtypes, disease stages and menopausal status.
3. To prepare a cost-utility analysis of the use of biomarker assays as part of a combined initial assessment of adnexal masses in a tertiary hospital setting.
4. To devise a protocol in preparation for local recommendations and practice guideline formulation for biomarker assays in the pre-surgical screening of adnexal masses.

II. OPERATION OF THE STUDY

The STUDY shall be undertaken by the UNIVERSITY through the Department of Physiology as main PROPONENT, in accordance with the approved protocol hereto attached as **Annex "I"** and made an integral part hereof.

III. OBLIGATIONS OF THE UNIVERSITY

The UPCM, through the PI, shall:

1. Submit to the SPONSOR the financial reports every six (6) months on schedule as indicated in Item V of this Agreement;
2. Manage the funds remitted by the SPONSOR according to the budget set forth in Item V which is an integral part of this Agreement;
3. Hire project/program personnel on contractual basis and co-terminus with this Agreement;

IV. OBLIGATIONS OF THE SPONSOR

The SPONSOR shall provide the amount of **three million three hundred three thousand pesos (P 3,303,000.00)** for implementation of the STUDY and release the subsequent funds according to the schedule stipulated in Section V of this Agreement;

V. LINE ITEM BUDGET AND FUND RELEASE

The SPONSOR shall release the STUDY funds to the UPCM, through the UPMAF, upon execution of this Agreement and subject to the following schedule and submission of required reports/outputs:

Tranche/Period of Coverage	Expected Output	Schedule of fund transmittal by the SPONSOR	Amount (Php)
<u>First Tranche:</u> (October 2017 - March 2017)	<u>Outputs:</u> Study Report 1 Financial Report 1 <u>Due date:</u> March 30, 2018	November 8, 2017	884,500.00
<u>Second Tranche:</u> (April 2018 – September 2018)	<u>Outputs:</u> Study Report 2 Financial Report 2 <u>Due date:</u> September 28, 2018	April 2, 2018	734,500.00
<u>Third Tranche:</u> (October 2018 – March 2019)	<u>Outputs:</u> Study Report 3 Financial Report 3	October 1, 2018	734,500.00

	<u>Due date:</u> March 29, 2019		
<u>Fourth Tranche:</u> (April 2019 – September 2019)	<u>Outputs:</u> Study Report 4 Financial Report 4 <u>Due date:</u> September 30, 2019	April 1, 2019	544,500.00
<u>Fifth Tranche:</u> (October 2019 – March 2020)	<u>Outputs:</u> Study Report 5 Financial Report 5 <u>Due date:</u> March 31, 2020	October 1, 2019	405,000.00
	Total		3,303,000.00

VI. FUND UTILIZATION

Funds released to the UPCM, through the UPMAR, shall be available for use within the approved STUDY duration, in accordance with the approved line-item budget (LIB) and subject to existing government accounting and auditing rules and regulations.

The realignment of STUDY funds shall only cover the following:

1. Realignment within the approved line-item budget
2. Transfer of funds from one expense item to another. This shall not exceed thirty-three percent (33%) of the approved expense item to be augmented, and,
3. Creation of additional items.

The PRINCIPAL INVESTIGATOR will be free to realign the budget according to the demands of the scheduled activities of the STUDY. The PRINCIPAL INVESTIGATOR can create additional items, transfer funds from expense item to another, as needed for the implementation of the STUDY.

VII. INTELLECTUAL PROPERTY

1. All intellectual properties produced by virtue of and pursuant to this Agreement shall be jointly owned by the creator, inventor and authors and the parties to this Agreement.
2. Any publication or report arising from the activities undertaken by virtue and pursuant to this Agreement shall clearly establish and identify the party/ies which provided the same funding as well as the names of authors, investors and researchers.
3. Both parties shall have the right to use all data and findings produced by virtue of and pursuant to the MOA for the enhancement of their academic or official functions and research programs however, the details of the research outputs which have a potential for patent and/or commercialization may not be disclosed without the mutual written agreement of the parties.

VIII. PROJECT/PROGRAM DURATION

The STUDY shall be completed within thirty (30) months, covering the period of October 1, 2017 to March 31, 2020.

For purposes of requiring compliance with the terms and conditions of this Agreement the effectivity of this Agreement shall be coterminous with the acceptance by the SPONSOR of the last reports required to be submitted.

IX. DISPUTE RESOLUTION

1. All disputes, controversies or claims arising out of relating to this contract, or about its breach, termination or invalidity shall be settled through negotiation and/or mediation within sixty (60) days from the receipt of a notice by the other party
2. All such conflicts which cannot be decided by negotiation and/or mediation shall be decided by arbitration in accordance with the rules or arbitration contained in the UNCITRAL Model Law as adopted in Republic Act No. 9285 or the ADR Law of 2004
3. For this purpose, there shall be three (3) arbitrators with each party appointing one each and those appointed selecting the third arbitrator who shall be the chair of the arbitral panel. The appointing

authority mentioned in the Article 6 of the UNCITRAL Model Law and Article 26 of Republic Act No. 9285 shall be the Chair of the Commission on Higher Education.

4. The place of arbitration shall be in UP Manila without prejudice to holding hearings in another place for the convenience of the witnesses that may be presented by the parties. The language of the arbitration shall be in English or Filipino.
5. Each party shall deposit half of the costs for arbitration panel without prejudice to recovering such costs that may be awarded in the Arbitration Award.
6. The exclusive venue of all court actions or requests for interim measures, should these become necessary, shall be in the City of Manila, Philippines.

X. EFFECTIVITY


This Agreement shall take effect upon its execution and shall be in full force and effect until the completion of the STUDY, unless sooner revoked or modified in writing by the parties after due notice.

This agreement defines the relationship of the parties and its provisions as sole guide. Any modification to this Agreement shall be embodied in a Supplemental Memorandum of Agreement duly signed by both parties.

IN WITNESS WHEREOF, the Parties have subscribed to this Agreement on the date and at the place first above written.

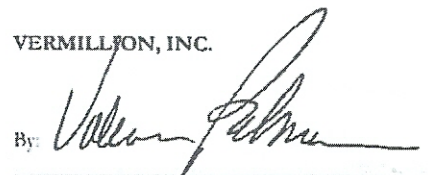
COLLEGE OF MEDICINE
UNIVERSITY OF THE PHILIPPINES
MANILA


By:

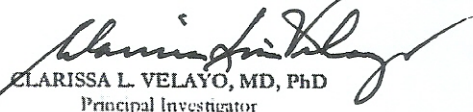

AGNES D. MEJIA, MD
Dean

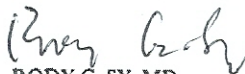
VERMILLION, INC.

By:


NAME OF SPONSOR REPRESENTATIVE
Designation *CEO*

Signed in the presence of

ELIZABETH S. MONTEMAYOR, MD, MSc
Chair
Department of Physiology, UPCM


CLARISSA L. VELAYO, MD, PhD
Principal Investigator
Associate Professor
Department of Physiology, UPCM


RODY G. SY, MD
President

University of the Philippines Medical Alumni Fund, Inc.

Republic of the Philippines)
(City of Manila) s.s.
CITY OF PASAY

ACKNOWLEDGEMENT

BEFORE ME, this **NOV 08 2017**, affiants exhibited to me their proof of identities indicated below:

Name	ID Number	Issued By/Date Issued
Agnes D. Mejia, MD	PAC 048394	PAC 12/11/78 SEP 5/4/2022

Known to me to be the same person who executed the foregoing instruments and acknowledged to me that the same is their free and voluntary act and deed and that of the institutions they respectively represent.

This Instrument refers to the memorandum of Agreement consisting of _____ pages including this page where the acknowledgement is written and signed by the parties and their witnesses.

CITY OF PASAY

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Book No. 28/7
Series of 2017

ATTY. HENRY D. ADASA
NOTARY PUBLIC CITY OF PASAY
UNTIL DECEMBER 31, 2017
NOTARIAL COMMISSION NO. 17-23
UNIT B J 11 BLDG. 1858 SEN. GIL PUYAT
AVE. COR. TRAMO PASAY CITY
IBP NO. 31047411 / 01/03/2017 Z.N.
PTR NO. 5405152 / 01/03/2017 MLA
MCLE COMPLIANCE NO. IV-6025957
② ROLL OF ATTORNEYS NO29679
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