

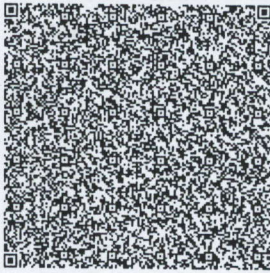


सत्यमेव जयते

# INDIA NON JUDICIAL Government of Karnataka

## e-Stamp

Certificate No.	: IN-KA313075344453930
Certificate Issued Date	: 27-Oct-2016 11:47 AM
Account Reference	: NONACC (FI)/ kacrsf108/ DERALAKATTE/ KA-DK
Unique Doc. Reference	: SUBIN-KAKACRSFL08123107534931540
Purchased by	: K S HEGDE MEDICAL ACADEMY DERALAKATTE MANGALORE
Description of Document	: Article 12 Bond
Description	: M O U
Consideration Price (Rs.)	: 0 (Zero)
First Party	: K S HEGDE MEDICAL ACADEMY DERALAKATTE MANGALORE
Second Party	: FATHER MULLER MEDICAL COLLEGE HOSPITAL MANGALORE
Stamp Duty Paid By	: K S HEGDE MEDICAL ACADEMY DERALAKATTE MANGALORE
Stamp Duty Amount(Rs.)	: 200 (Two Hundred only)



Authorized Signatory  
For Vijaya Credit Society Ltd  
DERALAKATTE

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## MEMORANDUM OF UNDERSTANDING

This Memorandum of Understanding (herein after referred to as "MOU") is made and executed on this date November 1, 2016 at Mangalore

*[Signature]*  
Dean  
K. S. Hegde Medical Academy  
DERALAKATTE, POST NITHYANANDA NAGAR  
MANGALORE - 575 018  
KARNATAKA

*[Signature]*  
Administrator  
Father Muller Medical College Hospital  
Fr. Muller Road, Kankanady  
MANGALORE-575002  
Karnataka State

- Statutory Declaration
1. The authenticity of this e-Stamp should be verified at "www.shcilestamp.com". Any discrepancy in the details on this Certificate and as available on the web renders it invalid.
  2. The onus of checking the legitimacy is on the users of the certificate.
  3. In case of any discrepancy please inform the Competent Authority.



## BY AND BETWEEN

K. S. Hegde Medical Academy, Deralakatte, Mangalore (a constituent college of Nitte University) situated at Nithyananda Nagar, Deralakatte, Mangalore – 575018 represented by Prof. (Dr.) B. Satheesh Kumar Bhandary, Dean (hereinafter referred to as “KSHEMA”) which term unless repugnant to the context thereof, shall mean and include its successors-in-interest and permitted assigns, of the FIRST PART

AND

Father Muller Medical College Hospital, Mangalore (a unit of Father Muller Charitable Institutions) situated at Father Muller Road, Kankanady, Mangalore – 575002 represented by Rev Fr. Richard Coelho, Administrator (hereinafter referred to as “FMMCH”) which term unless repugnant to the context thereof, shall mean and include its successors-in-interest and permitted assigns, of the SECOND PART

“KSHEMA” and “FMMCH” are individually and collectively referred to as “Party” and “Parties” respectively.

## WHEREAS

- KSHEMA centre for Genetic Services, a division of K. S. Hegde Medical Academy is a diagnostic genetic laboratory delivering specialized testing facilities in the field of Pediatrics, Obstetrics and Gynecology, Oncology & Pathology
- KSHEMA offers Inter Laboratory Quality Control specialized genetics diagnostic services on request from similar health care facilities.
- FMMCH owns and operates a hospital, requires services of the type offered by KSHEMA.
- FMMCH desires to obtain services from KSHEMA and KSHEMA is willing to provide such services to FMMCH, in accordance with the terms and conditions set forth within.

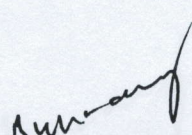
Wherefore, it is agreed between the Parties as under:

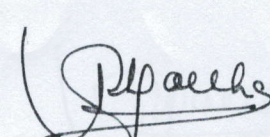
### 1. Term

1. This agreement shall be a valid for a period of three years from the date of execution of this agreement. This agreement shall come into effect from November 1, 2016. However either party will renew this agreement for further period of three years with mutual consent.

### 2. Objective

1. The objective of this MOU is to establish a written document framing a basic understanding under which both the parties shall be governed for conducting diagnostics and monitoring tests on the samples received from FMMCH.

  
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**Fr. Muller Road, Kankanady**  
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**Karnataka State**



### 3. Scope of Work

1. During the term hereof or the extended term as the case may be KSHEMA shall provide the services to FMMCH for all the tests requested by FMMCH. The list of tests annexed to this agreement as **Annexure 1**.

### 4. Role and Responsibilities of K. S. Hegde Medical Academy

- 4.1 KSHEMA shall conduct tests/investigations as per duly filled request form filled by FMMCH. The testing and reporting shall be carried out conforming to prevalent high standards of quality.
- 4.2 KSHEMA shall provide reports of tests/ investigations through e-mail to reduce the Turn Around time(TAT) and then hard copy by courier.
- 4.3 KSHEMA shall conduct tests/investigations on the basis of samples received from FMMCH. The sample received from FMMCH shall be tested and reported as per **Annexure 1**.

### 5. Roles and Responsibilities of Father Muller Medical College Hospital

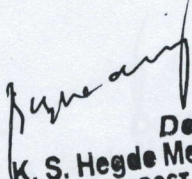
- 5.1 FMMCH shall be responsible for proper packing of samples and transportation in defined condition and temperature. KSHEMA will not be responsible for packing and transportation.
- 5.2 FMMCH shall be responsible for sending duly filled test requisition form, patient history, samples packing and labeling at required temperature in good condition to KSHEMA for test/ investigations.
- 5.3 FMMCH shall make payments to KSHEMA for services provided under this MOU within 15 days of receiving the invoices.
- 5.4 It is the responsibility of FMMCH to provide additional details requested by KSHEMA to conduct the test/ investigation.

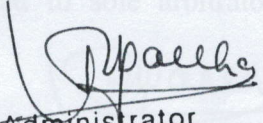
### 6. Force Majeure

- 6.1 Any event beyond the control of KSHEMA which prevents it from complying with its obligation to FMMCH resulting in delay in reporting or most performing to test shall be subject to majeure. These include but not limited to unavailability of test kits, failure of test, incomplete patient / test details, problem sample, need for repeat sample/ testing, instrument or machinery breakdown, civil unrest, riots, change in or in the interpretation of laws, strikes, lockout or other labour problems, unavailability of supply, fire or explosion, act of terrorism and other natural calamities.
- 6.2 KSHEMA would make efforts to mitigate the impact of such Force Majeure conditions and ensure timely testing as feasible and inform FMMCH accordingly.

### 7. Consideration:

- 7.1 The billing shall be done on monthly basis at rates as per the **Annexure 1** starting from 1<sup>st</sup> to 31<sup>st</sup> of each month and FMMCH undertakes to clear all the outstanding payments within 15 days from the date of receiving the invoices.

  
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**MANGALORE-575002**  
**Karnataka State**



7.2 Revision of tariff by KSHEMA will be intimated to FMMCH in writing, upon which the revised rate tariff shall be applicable from the date revision.

## 8. Termination and Consequences of Termination

8.1 Each of the parties makes the following representations and warranties to the other party hereto that the representing party has the full power and unrestricted authority to enter into this MOU. Entering this MOU and performing the obligations hereunder does not conflict with and is not prohibited under the terms of any other agreement, document, law, rule, regulation or court order to which the representing party is subject. Each of the parties has the full power and unrestricted authority to grant the licenses that are granted herein.

8.2 This MOU may be terminated on mutual consent or by either party with at least 30 days prior written notice without assigning any reasons.

8.3 All payments due, becoming due and payable to the Parties as on the date of termination, under the terms of this MOU shall continue to be due and payable to the Parties notwithstanding the termination hereof.

## 9. Confidentiality:

10.1 Each Party shall keep secret all Confidential Information, if any, transmitted to it or made available to it by the other Party and shall not pass such Confidential Information on, wholly or partly, to third parties without express written consent of the other Party.


10.2 The Parties shall not disclose the terms of this MOU or make any announcement in respect of the subject matter thereof without prior written consent of the other Party unless the disclosure is required by law or other regulatory authorities. In the event disclosure is required by law, rules or regulations, such disclosure shall be made after obtaining written permission of other party.

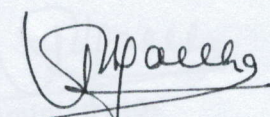
10.3 The Confidentiality obligations in this do not apply to disclose information that either Party in writing can prove that:

- i. It was known at the time of disclosure to be free of any obligation to keep it confidential, as evidenced by written records.
- ii. Became generally publicly known through authorized disclosure.
- iii. The information was independently developed without access to or use of any confidential Information, as evidenced by written records, or
- iv. The information was rightfully obtained from a third party who had the right to transfer or disclose it without violation of any confidentiality obligations.

## 10. Dispute Resolution and Governing Law

11.1 In case if any difference or dispute arises between the Parties herein, the Parties shall hold mutual discussions to resolve such difference and / or dispute in an amicable manner for the best interests of both Parties. Parties shall try to resolve the difference and / or dispute within 30 days or such extended time as agreed between the Parties. In case, any difference and / or dispute could not be resolved through mutual discussion then such difference and / or dispute between the Parties shall be referred to sole arbitrator

  
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**Karnataka State**



appointed by both the parties in accordance with the Arbitration and Conciliation Act, 1996. The venue of the arbitration shall be Mangalore. The award of the arbitration shall be final and binding between the Parties.

#### 11. Limitation of Liability

12.1 To the fullest extent permitted by Applicable Law neither Party nor its affiliates shall be liable for any special, indirect, consequential, or incidental damages (including but not limited to damages for loss of business profits, business interruption, loss of business information, and the like) arising out of this MOU even if either Party has been advised of the possibility of such damages.

#### 12.2 Miscellaneous:

Relationship: No provision of this MOU shall be deemed to constitute a partnership or joint venture between the Parties.

Further, each Party shall inform its employees that they shall not be treated as employees of the other Party for any purpose whatsoever and that they shall not exercise any rights or seek or be entitled to any benefits accruing to the regular employees of the other Party.

No provision of this MOU shall constitute either Party as the legal representative or agent of the other, nor shall either Party have the right or authority to assume, create or incur any liability or any obligation of any kind, express or implied, against or in the name of or on behalf of the other Party except as provided expressly under this Agreement.

#### 12. Notices:

Any notice required or permitted to be given hereunder shall be in writing and shall be effectively served.

13.1.1 If delivered personally, upon receipt by the other party;

13.1.2 If sent by prepaid courier service, airmail or registered mail, within seven (7) days of being sent; or

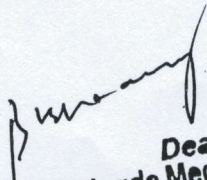
13.1.3 If sent by facsimile or other similar means of electronic communication (with confirmed receipt), upon receipt of transmission notice by the sender.

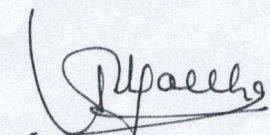
13.1.4 Any notice required or permitted to be given hereunder shall be addressed as given in the title to this MOU.

13.1.5 Any party hereto may change any particulars of its address for notice, by notice to the other in the manner aforesaid.

#### Violation of terms:

The Parties agree that each party shall be entitled to an injunction, restraining order, right for recovery, suit for specific performance, or such other equitable relief as a court of competent jurisdiction may deem necessary or appropriate to restrain the other party from permitting any violation or enforce the performance of the covenants, obligations and representations contained in this MOU. These injunctive remedies are cumulative and are in addition to any other rights and remedies the Parties may have at law or in equity, including without limitation, a right for recovery of the amounts due under this Agreement and related costs and a right for damages.

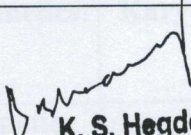
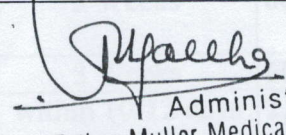
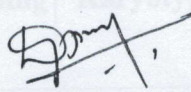
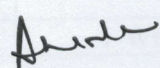
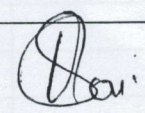
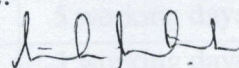
  
**Dean**  
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**KARNATAKA**

  
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**MANGALORE-575002**  
**Karnataka State**



# KSHEMA CENTRE FOR GENETIC SERVICES

IN WITNESS THEREOF the Parties have through their respectively duly authorized representatives, executed this MOU the day, month and year first hereinabove written.

Signed and delivered by KSHEMA K. S. Hegde Medical Academy	Signed and delivered by FMMCH Father Muller Medical College Hospital
 (Sign) <b>Dean</b> <b>K. S. Hegde Medical Academy</b> <b>DEVALAKATIE, POST NITHYANANDA NAGAR</b> <b>MANGALORE - 575012</b> <b>KARNATAKA</b> By: Prof. (Dr.) <b>K. S. Hegde</b> <small>Chief Executive Officer</small> Title: Dean	 (Sign) <b>Administrator</b> <b>Father Muller Medical College Hospital</b> <b>Chudro Road, Kankanady</b> <b>MANGALORE - 575002</b> <b>Karnataka State</b> By: Rev Fr. Richard <b>Chudro</b> Title: Administrator
Witness1:  (Sign) Name: <b>DR. D. PRASHANTH SHETTY.</b>	Witness1: (Sign)  Name: <b>DR. SHIVANIKAA</b>
Witness 2:  (Sign) Name: <b>Dr. Suehltha Kumari, N.</b>	Witness2: (Sign)  Name: <b>MS. LIDIA PAIS</b> <b>FINANCE OFFICER</b>

\*\*\*\*\*



**Annexure**  
**KSHEMA CENTRE FOR GENETIC SERVICES**

S.No	Test	Extent pf Test	Sample Required	Turn Around Time	Cost per test Rs.	EDP CODE
1	Clinical Cytogenetics:	Karyotyping	Blood in Sodium Heparin	12-15 days.	2,000/-	CHB199
			Skin Biopsy / Tumor Biopsy	3 Weeks	6000/-	CYG030
			Product of conception	3 Weeks	6000/-	CYG031
2	Cancer Cytogenetics - Leukemia's:	Karyotyping	Bone Marrow in Sodium Heparin	within 10-12 days	2,000/-	CYG001
3	Prenatal Karyotyping -	Karyotyping	Amniotic fluid (AF)	2 weeks	6000/-	CYG032
			Chorionic Villus samples (CVS)	2 Weeks	6000/-	CYG033
			Cord Blood (CB)	1 Week	3,000/-	CYG034

**Prenatal Cytogenetics (AF):FISH based Aneuploidy detection on uncultured Amniotic fluid**

1	LSI 13			5 working days	3,000/-	CYG002
2	LSI 21			5 working days	2,000/-	CYG003
3	CEP 18			5 working days	3,000/-	CYG004
4	LSI 13/21or18			5 working days	4,000/-	CYG005
5	CEP X / Y for post BMT			5 working days	3,000/-	CYG006
6	13/18/21			5 working days	6,000/	CYG007
7	13/18/21/X/Y			5 working days	9,000/-	CYG008

**Microdeletion syndromes – Blood sample culture and FISH**

1	DiGeorge / VCFS region probe		↓ Peripheral Blood Sample in Sodium Heparin ↑	7-10 working days	3,500/-	CYG009
2	Prader-Willi / Angelman region probe			7-10 working days	3,500/-	CYG010
3	Williams syndrome			7-10 working days	3,500/-	CYG011
4	DGS2 – 10p14			7-10 working days	3,500/-	CYG012
5	TelVysion 4p			7-10 working days	4,500/-	CYG013
6	TBX1			7-10 working days	3,500/-	CYG014
7	Ip36			7-10 working days	3,500/	CYG015



8	Wolf-Hirshhorn Syndrome		7-10 working days	3,500/-	CYG017
9	Smith-Magenis chromosome region probe		7-10 working days	3,500/-	CYG018
10	Miller Decker chromosome region probe		7-10 working days	3,500/-	CYG018

### Hematological Cancer – FISH on Bone Marrow

1	BCR / ABL single/double fusion – t (9; 22) – CML	<div style="text-align: center;"> ↓  Blood/Bone Marrow sample in Sodium Heparin  ↑ </div>	within 7-10 working days	4,000/-	CYG019
2	PML / RARA – t (15; 17) – AML / PML			4,000/-	CYG020
3	AML / ETO – t (11; 14)			4,000/-	CYG021
4	IGH/MYC, CEP 8 Tri-color, Dual Fusion – t (8, 14)			4,000/-	CYG022
5	IGH / CCND1 – t (11; 14)			4,000/-	CYG023
6	MYC dual color break apart – 8q24			4,000/-	CYG024
7	ETV6 (TEL) Break apart probe – 12p13			4,000/-	CYG025
8	7q22/7q36 Probe			4,000/-	CYG026
9	P53 Probe - 17p13			4,000/-	CYG027
10	DLEU/TP53 – 13q14/17p13			4,000/-	CYG028
11	MLL plus break apart probe – 11q23			4,000/-	CYG029

### Molecular Genetics Services

1	Gauchers	6 common mutations, exons 9 & 10	3-5ml of blood in EDTA	4 weeks	5,500/-	MLG001
2	Gauhers Prenatal	6 common mutations, exons 9 & 10	CVS Sample/Amniocentesis sample	4 weeks	7,500/-	MLG002
3	Gauchers	*prenatal diagnosis of Known mutation	CVS Sample/Amniocentesis sample	2 weeks	4,500/-	MLG003
4	Gauchers	Coding Sequence	3-5ml of blood in EDTA	8 weeks	9,500/-	MLG004
5	Glycogen Storage Disease 1a	All exons	3-5ml of blood in EDTA	6 weeks	7,000/-	MLG005



6	Glycogen Storage Disease 1a	*prenatal diagnosis of Known mutation	CVS Sample/Amniocentesis sample	2 weeks	4,500/-	MLG006
7	Glycogen Storage Disease 1b	All exons	3-5ml of blood in EDTA	6 weeks	7,500/-	MLG007
8	Glycogen Storage Disease 1b	prenatal diagnosis of Known mutation	CVS Sample/Amniocentesis sample	2 weeks	4,500/-	MLG008
9	Noonans Syndrome	PTPN11-exons 3 & 8	3-5ml of blood in EDTA	4 weeks	3,000/-	MLG009
10	Noonans Syndrome	PTPN11- All exons	3-5ml of blood in EDTA	10 weeks	13,500/-	MLG010
11	Noonans Syndrome	SOS 1-6 exons	3-5ml of blood in EDTA	6 weeks	6,500/-	MLG011
12	Noonans Syndrome	RAFI-3 exons	3-5ml of blood in EDTA	6 weeks	4,000/-	MLG012
13	XY-sex reversal	SRY	3-5ml of blood in EDTA	4 weeks	2,500/-	MLG013
14	Y microdeletions Azoospermia/ oligospermia	AZF <sub>a</sub> ,AZF <sub>b</sub> and AZF <sub>c</sub>	3-5ml of blood in EDTA	2 weeks	2,500/-	MLG014
15	Achondroplasia	FGFR3-Gly380Arg	3-5ml of blood in EDTA	4 weeks	2,500/-	MLG015
16	Fragile X	Presence of normal and permutation status	3-5ml of blood in EDTA	4 weeks	2,500/-	MLG016
17	Fragile X suspected positive sample confirmation	Sizing of CGG repeats for suspected positive samples	3-5ml of blood in EDTA	8 weeks	6,500/-	MLG017
18	Progressive Familial Intrahepatic cholestasis-1	PFIX 1-all exons	3-5ml of blood in EDTA	2 months	21,000/-	MLG018
19	Progressive Familial Intrahepatic cholestasis-1	PFIX 2-all exons	3-5ml of blood in EDTA	8 weeks	21,000/-	MLG019
20	β Thalassemia	All exons	3-5ml of blood in EDTA	4 weeks	4,000/-	MLG020
21	β Thalassemia- Prenatal Diagnosis package Parents+Fetus	All exons	CVS sample/Amniocentesis sample	3-4 weeks	13,000/-	MLG021
22	β Thalassemia	Prenatal Diagnosis Known mutation	CVS sample/Amniocentesis sample	2 weeks	4,500/-	MLG022
23	Costello Syndrome	HRAS -Exon 1	3-5ml of blood in EDTA	2 weeks	2,500/-	MLG023
24	Costello Syndrome	HRAS -coding sequences	3-5ml of blood in EDTA	4 weeks	5,500/-	MLG024



25	Maternal Cell Contamination of Fetal Sample	Two Loci	CVS sample/Amniocentesis sample	2 weeks	2,500/-	MLG025
26	Connexin 43	Coding sequence	3-5ml of blood in EDTA	4 weeks	2,500/-	MLG026
27	Spinal Muscular Atrophy	Exon 7 of SMN gene	3-5ml of blood in EDTA	4 weeks	3,500/-	MLG027
28	DNA Isolation and Storage		3-5ml of blood in EDTA	1 Week	1000/-	CYG035

**Contact Details:**

**(DR. PRASHANTH SHETTY)**  
**CO-ORDINATOR - GENETIC LABORATORY**  
**K S Hegde Medical Academy,**  
**Deralakatte, Mangalore – 575 018**  
**Ph – 2204491 Extn - 249**  
**Mobile - +91 - 9448348007**

**Dr. SUCHETHA KUMARI M.**  
 Professor  
 Department of Biochemistry  
 K.S. Hegde Medical Academy  
 Deralakatte, MANGALURU - 575 018  
 KARNATAKA, INDIA

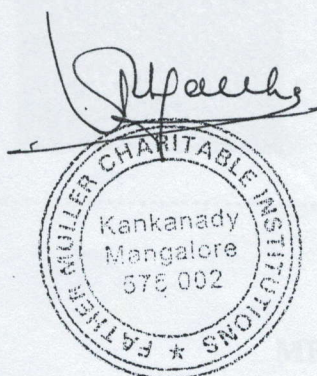
**Mobile: 9448451318**

**Mrs. Meenakshi A**  
**Mobile: 7829418612**



## Annexure- 1

<b>Biochemistry</b>	<b>Cost per test (Rs.)</b>
1) Anti TPO	910
2) CSF Glucose	75
3) CSF Protein	70
4) CSF Chloride	75
5) CSF ADA	400
6) Body fluid lactate	630
7) Body fluid ADA	400
8) Body fluid Chloride	75
9) Body fluid Glucose	75
10) Body fluid Protein	70
11) Body fluid LDH	225
12) Rheumatoid factor , turbidometry	105
13) CRP, Turbidometry	120
14) ASO, Turbidometry	160
15) Serum protein electrophoresis, automatted, Cellulose acetate.	380
16) Hb Electrophoresis, automatted	485
<b>Hematology and Clinical Pathology :</b>	
1) Fluid counts, body fluids	185
2) QBC	135
3) Bone marrow examination	550
4) Urine Bence Jones Protein	55
<b>Microbiology :</b>	
1) Procalcitonin assay	1600
2) Anti HBs Titre	520
3) PCR for Mycobacterium Tuberculosis, Gene XPert	1800
4) Anaerobic culture for bacteria	700



## MEMORANDUM OF UNDERSTANDING

This Memorandum of Understanding (hereinafter referred to as "MOU") is made and executed on this 1st day of January 2016 at Mangalore.

Administrator  
 Father Muller Medical College Hospital  
 P. O. Mangal Road, Kankanady  
 MANGALORE-575002  
 Karnataka State



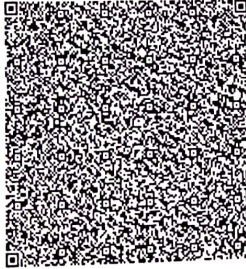


सत्यमेव जयते

# INDIA NON JUDICIAL Government of Karnataka

## e-Stamp

Certificate No.	: IN-KA003344871536070
Certificate Issued Date	: 26-Aug-2016 10:26 AM
Account Reference	: NONACC (FI)/ kaksfcl08/ KANKANADY/ KA-DK
Unique Doc. Reference	: SUBIN-KAKAKSFCL08508928918926620
Purchased by	: FATHER MULLER MEDICAL COLLEGE HOSPITAL
Description of Document	: Article 12 Bond
Description	: M O U
Consideration Price (Rs.)	: 0 (Zero)
First Party	: FATHER MULLER MEDICAL COLLEGE HOSPITAL
Second Party	: KASTURBA HOSPITAL
Stamp Duty Paid By	: FATHER MULLER MEDICAL COLLEGE HOSPITAL
Stamp Duty Amount(Rs.)	: 100 (One Hundred only)



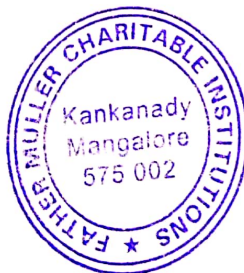
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## MEMORANDUM OF UNDERSTANDING

This Memorandum of Understanding (herein after referred to as "MOU") is made and executed on this date September 1st, 2016 till the date August 31st, 2017 at Mangalore

*[Signature]*

First Party



*[Signature]*

Second Party

CHIEF OPERATING OFFICER &  
MEDICAL SUPERINTENDENT  
KASTURBA HOSPITAL, MANIPAL

### Statutory Alert:

1. The authenticity of this Stamp Certificate should be verified at "www.shcilestamp.com". Any discrepancy in the details of the certificate available on the website renders it invalid.
2. The onus of checking the legitimacy is on the users of the certificate.



## BY AND BETWEEN

Father Muller Medical College Hospital, Mangalore (a unit of Father Muller Charitable Institutions) situated at Father Muller Road, Kankanady, Mangalore - 575002 represented by Rev Fr. Richard Coelho, Administrator (hereinafter referred to as "FMMCH") which term unless repugnant to the context thereof, shall mean and include its successors-in-interest and permitted assigns, of the FIRST PART  
AND Kasturba Hospital having its office at Madhavanagar, Manipal - 576104 duly represented by Dr. (Col) M Dayananda, Medical Superintendent & COO (hereinafter referred to as "Kasturba") which term unless repugnant to the context shall mean and include its successors and permitted assigns) of the SECOND PARTY

"FMMCH" and "Kasturba" are individually and collectively referred to as "Party" and "Parties" respectively.

## WHEREAS

1. Father Muller Medical College Hospital Laboratory, a division of Father Muller Medical College Hospital is a clinical laboratory delivering specialized testing facilities in the field of Biochemistry, Hematology, Histopathology and Microbiology.
2. FMMCH offers Inter Laboratory Quality Control specialized pathological diagnostic services on a per-request basis from similar health care facilities.
3. Kasturba owns and operates a hospital, requires services of the type offered by FMMCH.
4. Kasturba desires to obtain services from FMMCH and FMMCH is willing to provide such services to Kasturba, in accordance with the terms and conditions set forth within.

Wherefore, it is agreed between the Parties as under:

### 1. Term

- 1.1 This agreement shall be a valid for a period of one year from the date of execution of this agreement. This agreement shall come into effect from September 1st, 2016. However either party will renew this agreement for further period of one year with mutual consent.

### 2. Objective

- 2.1 The objective of this MOU is to establish a written document framing a basic understanding under which both the parties shall be governed for conducting diagnostics and monitoring tests on the samples received by Kasturba.

### 3. Scope of Work

- 3.1 During this one year term hereof or the extended term as the case may be FMMCH shall provide the services to Kasturba for all the tests (i.e. 2 samples per test for one year) requested by Kasturba. The list of tests annexed to this agreement as Annexure 1.

### 4. Role and Responsibilities of Father Muller Medical College Hospital

- 4.1 FMMCH shall conduct tests/investigations as per duly filled request form filled by Kasturba. The testing and reporting shall be carried out conforming to prevalent high standards of quality.

*[Signature]*



*[Signature]*  
CHIEF OPERATING OFFICER &  
MEDICAL SUPERINTENDENT,  
MANIPAL



- 4.2 FMMCH shall provide reports of tests/ investigations through hard copy by courier.
- 4.3 FMMCH shall conduct tests/investigations on the basis of samples received from Kasturba. The sample received from Kasturba shall be tested and reported within two or three working days under normal circumstances. Reporting timeliness will be in accordance with prevalent quality standards.

**5. Roles and Responsibilities of Kasturba**

- 5.1 Kasturba shall be responsible for proper packing of samples and transportation in defined condition and temperature. Hospital will not be responsible for packing and transportation.
- 5.2 Kasturba shall be responsible for sending duly filled test requisition form, patient history, samples packing and labeling at required temperature in good condition to FMMCH for test/ investigations.
- 5.3 Kasturba shall make payments to FMMCH for services provided under this MOU within 15 days of receiving the invoices.
- 5.4 It is the responsibility of Kasturba to provide additional details requested by FMMCH to conduct the test/ investigation.

**6. Force Majeure**

- 6.1 Any delay in reporting the test/ investigation shall be subject to Force Majeure, such as unavailability of test kits, failure of test, incomplete patient / test details, problem sample, need for repeat sample/ testing, instrument or machinery breakdown, civil unrest, riots, change in or in the interpretation of laws, strikes, lockout or other labour problems, unavailability of supply, fire or explosion, act of terrorism and other natural calamities. FMMCH would make efforts to mitigate the impact of such Force Majeure conditions and ensure timely testing as feasible and inform Kasturba accordingly.

**7. Consideration:**

- 7.1 The billing shall be done on case to case basis and Kasturba undertakes to clear all the outstanding payments within 15 days from the date of receiving the invoices.
- 7.2 Revision of tariff by FMMCH will be intimated to Kasturba in writing, upon which the revised rate tariff shall be applicable from the date revision.

**8. Termination and Consequences of Termination**

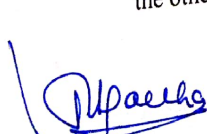

- 8.1 Each of the parties makes the following representations and warranties to the other party hereto that the representing party has the full power and unrestricted authority to enter into this MOU. Entering this MOU and performing the obligations hereunder does not conflict with and is not prohibited under the terms of any other agreement, document, law, rule, regulation or court order to which the representing party is subject. Each of the parties has the full power and unrestricted authority to grant the licenses that are granted herein.

**9. Termination and Consequences of Termination**

- 9.1 This MOU may be terminated on mutual consent or by either party with at least 30 days prior written notice without assigning any reasons.
- 9.2 All payments due, becoming due and payable to the Parties as on the date of termination, under the terms of this MOU shall continue to be due and payable to the Parties notwithstanding the termination hereof.

**10. Confidentiality:**

- 10.1 Each Party shall keep secret all Confidential Information, if any, transmitted to it or made available to it by the other Party and shall not pass such Confidential Information wholly or partly to third parties without express written consent of the other Party.

 **CHIEF OPERATING OFFICER & INCHARGE**



10.2 The Parties shall not disclose the terms of this MOU or make any announcement in respect of the subject matter thereof without prior written consent of the other Party unless the disclosure is required by law or other regulatory authorities. In the event disclosure is required by law, rules or regulations, such disclosure shall be made after obtaining written permission of other party.

10.3 The Confidentiality obligations in this do not apply to disclose information that either Party in writing can prove that:

- i. It was known at the time of disclosure to be free of any obligation to keep it confidential, as evidenced by written records.
- ii. Became generally publicly known through authorized disclosure.
- iii. The information was independently developed without access to or use of any confidential Information, as evidenced by written records, or
- iv. The information was rightfully obtained from a third party who had the right to transfer or disclose it without violation of any confidentiality obligations.

#### 11. Dispute Resolution and Governing Law

11.1 In case if any difference or dispute arises between the Parties herein, the Parties shall hold mutual discussions to resolve such difference and / or dispute in an amicable manner for the best interests of both Parties. Parties shall try to resolve the difference and / or dispute within 30 days or such extended time as agreed between the Parties. In case, any difference and / or dispute could not be resolved through mutual discussion then such difference and / or dispute between the Parties shall be referred to sole arbitrator appointed by both the parties in accordance with the Arbitration and Conciliation Act, 1996. The venue of the arbitration shall be Mangalore. The award of the arbitration shall be final and binding between the Parties.

#### 12. Limitation of Liability

12.1 To the fullest extent permitted by Applicable Law neither Party nor its affiliates shall be liable for any special, indirect, consequential, or incidental damages (including but not limited to damages for loss of business profits, business interruption, loss of business information, and the like) arising out of this MOU even if either Party has been advised of the possibility of such damages.

#### 13. Miscellaneous:

Relationship: No provision of this MOU shall be deemed to constitute a partnership or joint venture between the Parties.

Further, each Party shall inform its employees that they shall not be treated as employees of the other Party for any purpose whatsoever and that they shall not exercise any rights or seek or be entitled to any benefits accruing to the regular employees of the other Party.

No provision of this MOU shall constitute either Party as the legal representative or agent of the other, nor shall either Party have the right or authority to assume, create or incur any liability or any obligation of any kind, express or implied, against or in the name of or on behalf of the other Party except as provided expressly under this Agreement.

#### Notices:

Any notice required or permitted to be given hereunder shall be in writing and shall be effectively served.

13.1.1 If delivered personally, upon receipt by the other party;

13.1.2 If sent by prepaid courier service, airmail or registered mail, within seven (7) days of being sent; or





13.1.3 If sent by facsimile or other similar means of electronic communication (with confirmed receipt), upon receipt of transmission notice by the sender.

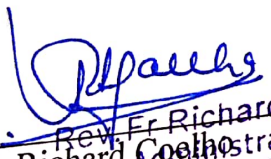

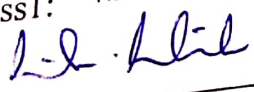
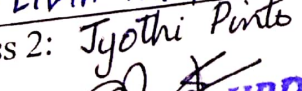

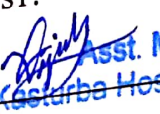
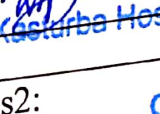
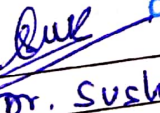
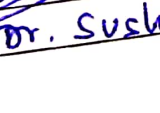
13.1.4 Any notice required or permitted to be given hereunder shall be addressed as given in the title to this MOU.

13.1.5 Any party hereto may change any particulars of its address for notice, by notice to the other in the manner aforesaid.

### Violation of terms:

The Parties agree that each party shall be entitled to an injunction, restraining order, right for recovery, suit for specific performance, or such other equitable relief as a court of competent jurisdiction may deem necessary or appropriate to restrain the other party from permitting any violation or enforce the performance of the covenants, obligations and representations contained in this MOU. These injunctive remedies are cumulative and are in addition to any other rights and remedies the Parties may have at law or in equity, including without limitation, a right for recovery of the amounts due under this Agreement and related costs and a right for damages.

**IN WITNESS THEREOF** the Parties have through their respectively duly authorized representatives, executed this MOU the day, month and year first hereinabove written.

Signed and delivered by FMMCH Father Muller Medical College Hospital	Signed and delivered by Kasturba Kasturba Hospital, Madhavanagar, Manipal
(Sign)  By: Rev Fr. Richard Coelho Title: Administrator Father Muller Medical College Hospital Father Muller Road Kankanady, Mangalore-575 002	(Sign)  By: Dr. (Col) M. Dayananda Title: Medical Superintendent & COO KASTURBA HOSPITAL, MANIPAL
Witness1:  (Sign)  Name: LIDIA PAIS, FINANCE OFFICER Witness 2: Jyothi Pinto (Sign)  Name: Manager-HRD Father Muller Charitable Institutions Kankanady, Mangalore-575 002	Witness1:  (Sign)  Name: Vijish V K Asst. Manager - Quality Kasturba Hospital, Manipal - 576 104 Witness2:  (Sign)  Name: Dr. Sushma Belurkar OFFICER-IN-CHARGE CLINICAL LABORATORY KASTURBA HOSPITAL MANIPAL





**MEMORANDUM OF UNDERSTANDING**

This Memorandum of Understanding (herein after referred to as "MOU") is made and executed on this, date 22<sup>nd</sup> November 2016 at Bangalore.

**BETWEEN**

Manipal Hospital, Bangalore a unit of Manipal Health Enterprises Private Limited situated at # 98, HAL airport road , Bangalore 560017, represented by Mr. Pramod Alagharu, Regional Head-Operations (hereinafter referred to as 'MANIPAL'), which expression unless repugnant to the context thereof, shall mean and include its successors-in-interest and permitted assigns, of the One Part;

**AND**

Father Muller Medical College Hospital, Father Muller Road, Kankanady, Mangalore - 575 002, represented by Rev. Fr Richard Coelho, Administrator (hereinafter referred to as "Client" which expression unless repugnant to the context shall mean and include its legal representatives, affiliate, subsidiary Company, administrators, executors, nominee and assigns of the Other Part;

"Manipal" and "Client" are individually and collectively referred to as "Party" and "Parties" respectively.

**WHEREAS:**

- A. Department of Laboratory Medicine, a division of Manipal Hospital Bangalore is a clinical laboratory delivering specialized testing facilities in the field of Biochemistry, Transfusion Medicine services, Hematology, Histopathology, Microbiology, Molecular Pathology, Nephropathology and Medical Genetics services.
- B. Manipal Hospital offers Inter Laboratory Comparison & as Referral Laboratories services on a per-request basis from similarly-situated health care facilities.
- C. Client owns and operates a hospital, requires Services of the type offered by the Manipal Hospital.
- D. Client desires to obtain Services from the Manipal Hospital and the Manipal Hospital is willing to provide such Services to Client, in accordance with the terms and conditions set forth herein.

Manipal Hospital HAL Airport Road

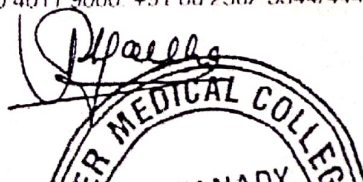
98, HAL Airport Road, Bengaluru 560017 P +91 80 4011 9000 +91 80 2502 3344/4444 www.manipalhospitals.com



☎ 2222 1111

Registered Office

Manipal Health Enterprises Pvt Ltd







NOW THEREFORE THE PARTIES TO THE MOU WITNESS AS UNDER:

1. Term

1.1 This agreement shall be valid for a period of two year from the date of execution of this agreement. This agreement shall come in to effect from 22<sup>nd</sup> November 2016. However either party will renew this agreement for further period of one year with mutual consent.

2. Objective:

2.1 The objective of this MOU is to establish a written document framing a basic understanding under which both the parties shall be governed for conducting diagnostics and monitoring tests on the samples received by the Client.

3. Scope of Work:

3.1 During the term hereof or the extended term as the case may be Manipal Hospital shall provide the services to Client for all test requested by Client. The list of the Tests annexed to this agreement as Annexure A.

4. Role and Responsibilities of Manipal Hospital.

4.1 Manipal Hospital shall conduct test/investigations, as per the duly filled request form filled by Client. The testing and reporting shall be carried out conforming to prevalent high standards of quality

4.2 Manipal Hospital shall provide reports of test/investigation conducted through E-mail. The hard copy of report may be couriered or collected by Client on specific request by the Client.

4.3 Manipal Hospital shall conduct test/investigation on the basis of samples received from Client. Upon receipt of the sample from the Client will be tested and reported within 2-3 working days under normal circumstances. Reporting timeliness will be in accordance with prevalent quality standards

4.4 For any query related to technical issues for Hospital other issues relating to billing will be handled by Lab Manager & Lab Officer (ph. No. 080-25023399).

5. Role and Responsibilities of Client:

Manipal Hospital HAL Airport Road

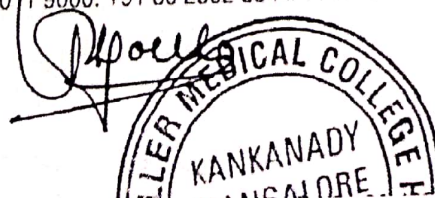
HAL Airport Road, Bengaluru 560017 P | 91 80 4011 9000. | 91 80 2502 3344/4444 www.manipalhospitals.com



2222 1111

Registered Office

Manipal Health Enterprises Pvt Ltd







5.1 Samples will be pickup by Manipal Hospital by - Department of laboratory Medicine with written Test Request Form

5.2 Client shall be responsible for proper packing of samples and transportation in defined condition and temperature. Hospital will not be responsible for packing and transportation.

5.3 Client shall be responsible for sending duly filled Test Requisition Form, Patient History, samples packing and labeling at required temperature in good condition to Manipal Hospital for test/investigation.

5.4 Client shall make payments to Manipal Hospital for services provided under this MOU within 10 days of receiving the invoices.

5.5 Its on responsibility of Client to provide additional details requested by Manipal Hospital to conduct the test/investigation.

## 6. Force Majeure:

6.1 Any delay in reporting the test/investigation shall be subject to Force Majeure, such as unavailability of test kits, failure of test, incomplete patient / test details, problem sample, sample lost in transit, need for repeat sample/testing, instrument or machinery breakdown, civil unrest, riots, change in or in the interpretation of laws, strikes, lockout or other labor problems, unavailability of supply, fire or explosion, act of terrorism and other natural calamities. In the event of repeat sample/testing requirement, MH would agree to repeat the test at its own cost. Manipal Hospitals would also make efforts to mitigate the impact of such Force Majeure conditions and ensure timely testing as feasible and inform the client accordingly.

## 7. Consideration

7.1 The billing shall be done on monthly basis starting from 1<sup>st</sup> to 31<sup>st</sup> of each month and Client undertakes to clear all the outstanding payments within 15 days from the date of receiving the invoices.

7.2 Consideration for the services is mentioned in Annexure II.

7.2 Revision of tariff by Manipal Hospital will be intimated to Client in writing, upon which the revised rate tariff shall be applicable from the date of Client accepting the same in writing.

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For any medical emergency



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MANIPAL HOSPITALS







8. Representations and Warranties of the Parties

8.1 Each of the parties makes the following representations and warranties to the other party hereto that the representing party has the full power and unrestricted authority to enter into this MOU. Entering this MOU and performing the obligations hereunder does not conflict with and is not prohibited under the terms of any other agreement, document, law, rule, regulation or court order to which the representing party is subject. Each of the parties has the full power and unrestricted authority to grant the licenses that are granted herein.

9. Termination and Consequences of Termination

9.1 This MOU may be terminated on mutual consent or by either party with at least 30 days prior written notice without assigning any reasons.

9.2 All payments due, becoming due and payable to the Parties as on the date of termination, under the terms of this MOU shall continue to be due and payable to the Parties notwithstanding the termination hereof.

10. Confidentiality

10.1 Each Party shall keep secret all Confidential Information, if any, transmitted to it or made available to it by the other Party and shall not pass such Confirmation Information on, wholly or partly, to third parties without express written consent of the other Party.

10.2 The Parties shall not disclose the terms of this MOU or make any announcement in respect of the subject matter thereof without prior written consent of the other Party unless the disclosure is required by law or other regulatory authorities. In the event disclosure is required by law, rules or regulations, such disclosure shall be made after obtaining written permission of other party.

10.3 The Confidentiality obligations in this do not apply to disclosed information that either Party in writing can prove that:

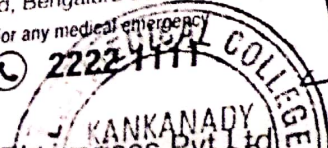
- i. It was known at the time of disclosure to be free of any obligation to keep it confidential, as evidenced by written records;
- ii. Became generally publicly known through authorized disclosure;
- iii. The information was independently developed without access to or use of any confidential Information, as evidenced by written records; or

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- iv. The information was rightfully obtained from a third party who had the right to transfer or disclose it without violation of any confidentiality obligations.

## 11. Dispute Resolution and Governing Law

11.1 In case of any difference or dispute arises between the Parties herein, the Parties shall hold mutual discussions to resolve such difference and/or dispute in an amicable manner for the best interests of both Parties. Parties shall try to resolve the difference and / or dispute within 30 days or such extended time as agreed between the Parties. In case, any difference and / or dispute could not be resolved through mutual discussion then such difference and / or dispute between the Parties shall be referred to sole arbitrator appointed by both the parties in accordance with the Arbitration and Conciliation Act, 1996. The venue of the arbitration shall be Bangalore. The award of the arbitration shall be final and binding between the Parties.

## 12. Limitation of Liability

12.1 To the fullest extent permitted by Applicable Law neither Party nor its affiliates shall be liable for any special, indirect, consequential, or incidental damages (including but not limited to damages for loss of business profits, business interruption, loss of business information, and the like) arising out of this MOU even if either Party has been advised of the possibility of such damages.

## 13. Miscellaneous

### Relationship:

No provision of this MOU shall be deemed to constitute a partnership or joint venture between the Parties.

Further, each Party shall inform its employees that they shall not be treated as employees of the other Party for any purpose whatsoever and that they shall not exercise any rights or seek or be entitled to any benefits accruing to the regular employees of the other Party.

No provision of this MOU shall constitute either Party as the legal representative or agent of the other, nor shall either Party have the right or authority to assume, create or incur any liability or any obligation of any kind, express or implied, against or in the name of or on behalf

Manipal Hospitals Pvt. Ltd. provided expressly under this Agreement.

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*[Handwritten signature]*



Registered Office

Manipal Health Enterprises Pvt. Ltd.





## Notices:

Any notice required or permitted to be given hereunder shall be in writing and shall be effectively served

- 13.1.1 If delivered personally, upon receipt by the other Party;
- 13.1.2 If sent by prepaid courier service, airmail or registered mail, within five (5) days of being sent; or
- 13.1.3 If sent by facsimile or other similar means of electronic communication (with confirmed receipt), upon receipt of transmission notice by the sender.
- 13.1.4 Any notice required or permitted to be given hereunder shall be addressed to the address as given in the title to this MOU.
- 13.1.5 Any Party hereto may change any particulars of its address for notice, by notice to the other in the manner aforesaid.

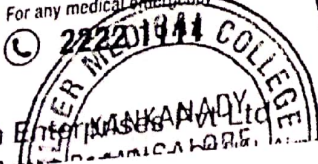
## Violation of Terms:

The Parties agree that each Party shall be entitled to an injunction, restraining order, right for recovery, suit for specific performance, or such other equitable relief as a court of competent jurisdiction may deem necessary or appropriate to restrain the other Party from committing any violation or enforce the performance of the covenants, obligations and representations contained in this MOU. These injunctive remedies are cumulative and are in addition to any other rights and remedies the Parties may have at law or in equity, including without limitation, a right for recovery of the amounts due under this Agreement and related costs and a right for damages.

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For any medical emergency



Registered Office


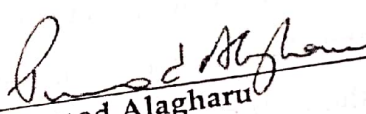
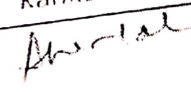
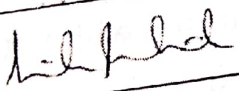
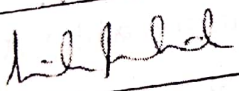
Manipal Health Enterprises Pvt. Ltd.







IN WITNESS WHEREOF the Parties have through their respectively duly authorized representatives, executed this MOU the day, month and year first hereinabove written.

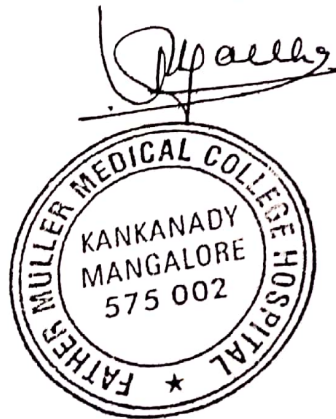
Signed & Delivered by CLIENT		Signed & Delivered by MHEPL	
Father Muller Medical College Hospital		Manipal Health Enterprises Private Limited	
(Sign) 		(Sign) 	
By: Rev. Fr Richard Coelho		By: Mr. Pramod Alagharu	
Administrator		Title: Regional Head	
Father Muller Medical College Hospital		Witness 1:	
Father Muller Road		(Sign)	
Kankanady, Mangalore-575 002		Name	
Witness 1: 		Witness 2:	
(Sign)		(Sign)	
Name 		Name	
Witness 2: 			
Name M. LIDIA PAIS			





ANNEXURE II  
(Consideration)

Manipal Hospital Laboratory will extend Institutional discount of 30% to M/S Father Muller Medical College Hospital on MRP for all tests other than the tests of Medical Genetics which is applicable a discount of 15% on MRP conducted in Manipal Hospital Genetics Laboratory.





## AGREEMENT FOR CLINICAL TRIALS BY SITE

THIS MASTER AGREEMENT FOR CLINICAL TRIALS BY SITE (hereinafter referred to as this "**Agreement**") is made on this 12<sup>th</sup> day of the month of September in the year 2017 ("**Effective Date**"), by and between

**Dr. Reddy's Laboratories Limited**, a company registered under the Companies Act, 1956 and having its registered office at 8-2-337, Road No. 3, Banjara Hills, Hyderabad, Telangana – 500034, India (hereinafter referred to as "**SPONSOR**", which expression shall unless contrary the meaning and context thereof mean and include its successors, representative and permitted assigns) of One Part;

And

**Father Muller Medical College Hospital**, a unit of Father Muller Charitable Institution registered under laws of India and located at Kankanady, Mangalore. Karnataka-575002(hereinafter referred to as "**INSTITUTION**" which expression shall unless contrary the meaning and context thereof mean and include its successors, representatives and permitted assigns) of the Second Part;

And

**Dr. Jacintha Martis** an individual, having an address at Father Muller Medical college Hospital, Kankanady, Mangalore. Karnataka-575002 will serve as the principal investigator ("**Principal Investigator**")

Collectively Principal Investigator and Institution (with its personnel, officers, board members, affiliates, Site Management Organization, and agents) shall be referred to as the "**SITE**".

Within this Agreement, SPONSOR and SITE are individually referred to as the "**Party**" and jointly as "**Parties**"

### RECITALS

- A. **WHEREAS** SPONSOR researches, develops, manufactures and distribute a range of pharmaceutical products in a variety of therapeutic use;
- B. **WHEREAS**, SITE, acting as an independent contractor, desires to conduct clinical research studies ("**the Study**"), according to SPONSOR's Clinical Trial Protocol ("**Protocol**") and as agreed to by all the Parties;
- C. **WHEREAS**, SPONSOR requires a clinical trial to be performed in relation to an investigational product ("**Investigational Product**");
- D. **WHEREAS**, SITE has established and maintains a clinical trial study service, and has acquired expertise in conducting research evaluations, clinical trials, and laboratory test evaluations;



- E. WHEREAS, SPONSOR wishes to engage the SITE to carry out the Study;
- F. WHEREAS, SITE has sufficient authority, competence and experience in conducting clinical trials and, having reviewed the Protocol, the investigator brochure, and sufficient information regarding the Investigational Product related to the Study, desires to so participate in the Study as more particularly described in this Agreement. For the purposes of clarity, SITE has acquired the necessary clearances as per applicable laws for initiating or conducting any studies;
- G. WHEREAS, SITE is willing to undertake the Study for SPONSOR according to the terms, conditions and covenants hereinafter set forth; and
- H. WHEREAS SITE has agreed to provide the services to SPONSOR on the terms of this Agreement.

NOW THEREFORE THIS AGREEMENT WITNESSETH, that in consideration of the mutual covenants herein contained and other good and valuable consideration exchanged between the Parties, the receipt and sufficiency whereof is hereby acknowledged by the Parties hereto, the parties covenant and agree as follows:

**ARTICLE 1: Study**

- 1.1 SITE will perform the Study as detailed in Annexure 1 of this Agreement in compliance with the terms of this Agreement.

**ARTICLE 2: Period of Performance**

- 2.1 The performance of this Agreement shall be from the Effective Date through completion of the Study, unless terminated earlier in accordance with Article 12 of this Agreement. This Agreement may be extended by the written agreement of the Parties.

**ARTICLE 3: Conduct of the Study**

- 3.1 The SITE agrees to perform the Study detailed in Annexure 1 hereto in strict accordance with the Protocol, the terms and conditions of this Agreement and any amendments thereto, and all federal, state and local laws and regulations applicable to the performance of the Study and this Agreement in the territory where the Study is performed, including but not limited to (a) Good Laboratory Practice, the revised and applicable versions of the Declaration of Helsinki Directive 95/46/EC; and (b) the International Conference on Harmonization of Technical Requirements for Registration of Pharmaceuticals for Human Use Topic E6: Guidelines on Good Clinical Practice and Directive 75/318/EEC, as amended from time to time ("ICH/GCP"); (collectively, "Applicable Law").



- 3.2. The Study will be supervised by the Principal Investigator, who will be employed/engaged, as applicable, by Institution, and who will personally be responsible for the direction of the research and the conduct of the Study in accordance with the applicable policies of the Institution, which the Principal Investigator represent and warrant are not inconsistent with (1) the terms of this Agreement, (2) the Protocol, (3) generally accepted standards of good clinical practice, and (4) Applicable Law. Principal Investigator shall conduct the Study and use his/her best efforts to complete the Study in a professional manner in accordance with the highest standards in the industry and in strict adherence to sub-parts (1) – (4) of this Article 3.2. If the Study is conducted by a team of individuals including Sub-investigator(s), the Principal Investigator shall be responsible for all Sub-investigators and Study team members utilized in any manner, in connection with the Study, and SITE shall instruct each Sub-investigator and team member to follow the direction of the SITE and otherwise adhere strictly to the Protocol. Institution shall ensure that Principal Investigator shall not delegate his/her responsibility to personally supervise the Study without Institution's prior written approval. Institution further agrees to ensure that Principal Investigator and/or any sub-investigators: (i) are fully informed of the Protocol, the Investigational Product; and (ii) participates in all investigator meetings and telephone conferences as required for the conduct of the Study. Institution will further ensure that Principal Investigator, sub-investigator, and any other personnel involved with the Study, participate in training sessions as necessary for the performance of the Study.
- 3.3 Institution/Principal Investigator will notify SPONSOR immediately if Principal Investigator is unable to continue as principal investigator for the Study. SITE further agrees that no other investigator may be substituted for the Principal Investigator without the prior written approval of SPONSOR and the ethics committee. If for any reason, Principal Investigator is unable to serve as principal investigator, and a successor acceptable to SPONSOR is not available, the SPONSOR may terminate this Agreement.
- 3.4 SITE shall ensure that Study subjects have agreed to participate in the Study as defined by the Protocol and in compliance with Applicable Law. SITE shall further ensure that the Study subjects are adequately informed of the aims, methods, anticipated benefits and potential hazards of the Study and the circumstances under which their personal data might be disclosed to relevant third parties including, but not limited to, SITE, SPONSOR and/or its affiliates, competent authorities, and/or ethics committees, in accordance with the requirements for such information as set forth in the Protocol prior to including any subject in the Study. SITE shall obtain the informed consent of subjects to participate in the Study prior to said participation, and shall document the Study subjects' informed consent by securing from each patient, his or her signature upon an informed consent form, that complies with Applicable Law, a copy of which shall be retained by the SITE. The Study subject shall also receive a signed copy of the informed consent. Further, the name, medical history, and any and all information relating to a Study patient obtained as a result of or in connection with his or her participation in the Study shall be held in strictest confidence and trust, and shall not be disclosed or transferred to third parties except as expressly permitted by this Agreement or the Protocol.



- 3.5 **Adverse Events.** SITE shall report to SPONSOR, any death, life threatening, or serious adverse event, or other event as specified by the Protocol. Such notification shall be given promptly, and in no instance later than twenty-four (24) hours of becoming aware of such an event and shall be made in accordance with the procedures outlined in the Protocol concerning the reporting of adverse events and serious adverse events.
- 3.6 No changes or revisions in the Protocol shall be made unless first mutually agreed upon in writing by SPONSOR and SITE, and reviewed and approved by the Applicable Authority in accordance with Applicable Law or where deemed necessary to protect the safety, rights or welfare of any subjects entered into the Study, in which case SPONSOR will be immediately notified in writing of such action and necessity for deviation from the Protocol. If any changes in the Protocol affect the charge for research conducted in the Study, SITE shall submit a written estimate of the charges for SPONSOR'S prior written approval.

#### **ARTICLE 4: Payment**

##### **4.1 Fees**

- 4.1.1 Fees mentioned in Annexure 1 are exclusive of GST, VAT, sales or similar withholding taxes. The SITE will provide its reasonable co-operation to SPONSOR to ensure that SPONSOR is only required to pay GST, VAT, sales or similar withholding taxes once, in accordance with Applicable Laws and where permitted, to minimise duplication of such taxes. All other taxes are the SITE's responsibility;
- 4.1.2 If any payments made by the Parties under this Agreement become subject to withholding taxes under Applicable Law of any state, central or foreign government, each Party shall be authorised to withhold such taxes as are required under Applicable Law, pay such taxes to the appropriate government authority, remit the balance due to the other Party net of such taxes, and provide a certificate as provided by the appropriate government authority towards this effect to the other Party. The Parties agree to cooperate in good faith to qualify the transactions for any exemptions or reductions in the amount of otherwise applicable withholding tax provided under Applicable Law (including the provisions of any relevant tax treaty) and to complete such forms as necessary for such purpose.
- 4.1.3 The quotation provided by SITE for a Study shall be optimal and on a fixed cost basis for both administrative cost and pass through costs except when mutually agreed upon by both parties. Parties acknowledge and agree that the Fees along with expenses quoted by SITE will be an upper limit of the estimated quote and has been arrived at, on the basis of the Study scope, requirements and allocation of resources for conducting the Study.
- In the event that, the Parties believe that due to change in the Study scope, or resource re-allocation requirements, there is a need for upward or downward revision of the Study quote, SITE shall inform SPONSOR in writing and Parties shall mutually agree to modify the Agreement accordingly.
- 4.1.4 the Fees are fixed and will not be varied without SPONSOR' prior written consent;
- 4.1.5 the Fees include all performance requirements of this Agreement; and



4.1.6 The timelines provided by SITE for the completion of a Study shall be optimal and explain the best case scenarios for achievement of timelines.

#### **4.2 Invoicing and Payment**

4.2.1 The SITE will invoice SPONSOR in accordance with the terms mentioned herein or as per the milestones set in the agreement. Each invoice will specify the SPONSOR Study Code / Purchase Order provided by SPONSOR.

4.2.2 The SITE must provide appropriate supporting documentation to substantiate the amount charged, on request by SPONSOR.

4.2.3 SPONSOR will pay the Fees within forty-five (45) days of the receipt of a correct and valid invoice or as per the milestones set in the agreement, subject to the satisfactory completion of associated Deliverables.

4.2.4 SPONSOR will pay the undisputed portion of an invoice and may withhold payment on the disputed portion until resolved.

4.2.5 The SITE agrees that the Fees:

- i. represent fair-market value for the Services or for conducting the Study;
- ii. do not create any obligation to prescribe, supply, administer, recommend or buy SPONSOR' products or constitute any reward for past or future business; and
- iii. do not represent any inducement to influence the SITE to push for or prescribe, supply, administer, recommend or buy SPONSOR' products.

#### **ARTICLE 5: Record Keeping and Access**

5.1 SITE shall ensure that:

5.1.1 It prepares, maintains and retains complete, current, organized, and legible Study documents relating to its performance of the Study which are required to be retained under Applicable Law, and any other records pertaining to the Study subjects who have participated in any way, in the Study including, without limitation, source documents monitoring Study subjects' progress, medical and clinical records and complete case report forms ("CRFs") (collectively, "**Study Records**") for each Study patient no later than three (3) days after a visit or as per protocol. SITE shall respond to all data queries within three (3) days from the date of such request. SITE will ensure that all personnel take appropriate measures to prevent unauthorized access to the electronic data capture system including maintaining confidentiality of their passwords. Study Records will be retained by the SITE for five (5) years following the date a marketing application is approved for the Investigational Product for the indication under investigation in the Study, or if no application is to be filed, or if the application is not approved for such indication, until five (5) years after the investigation is discontinued and the applicable regulatory authority is notified, or any longer retention period mandated by Applicable Law.



- 5.1.2 SITE maintains written adequate records of the disposition of the Investigational Product, including dates, quantity and use by Study subjects according to Applicable Law, as amended from time to time, and any successor regulations), the Protocol, or as otherwise established by written notice from SPONSOR, showing the receipt, administration, or other disposition of the Investigational Product.
- 5.1.3 SITE prepares and maintains adequate and accurate subjects case histories recording all observations and other data pertinent to the clinical Study of each patient enrolled as a subject in the clinical investigation of the Investigational Product.
- 5.1.4 SITE retains the records and reports required by Applicable Law as amended from time to time, and any successor regulations, and the Protocol, and shall deliver copies of the same to SPONSOR as required by the Protocol.
- 5.2 Authorized representative(s) of SPONSOR, shall be allowed during regular business hours, and at reasonable intervals, to examine and inspect SITE facilities utilized in the performance of the Study, and to inspect and copy all Study data, records, and work products related to the Study, for purposes of assuring compliance with Applicable Laws, the Protocol, and the terms of this Agreement. Audits shall be at no additional cost to SPONSOR provided such audits are at mutually agreed intervals and do not significantly alter Institution's ability to meet any deadlines delineated in this Agreement.

#### **ARTICLE 6: Publications**

- 6.1 SPONSOR shall be solely responsible for determination whether to submit the Study for listing in a publicly accessible clinical trial registry or any equivalent registry SPONSOR deems appropriate, prior to initiation of any Study patient enrolment. For greater certainty, SITE, shall not register the Study or Study results on any publicly accessible clinical trial registry. Where applicable, SITE shall ensure that a non-promotional summary of the results of the Study or a citation or link to a peer-reviewed article in a medical journal where one exists, will be posted on a free publicly accessible clinical trial results database within one (1) year after the Investigational Product is first approved and made commercially available in any country or, if the Study is under review by a peer-review journal that prohibits disclosure of results pre-publication, as soon as practicable after publication.
- 6.2 SITE hereby acknowledge and agrees that the SPONSOR has the right to use the Study results in any manner deemed appropriate to SPONSOR's business interests, both during, and following termination of this Agreement and/or the Study.
- 6.3 In the event Study is not part of a multi-centre study or where no multi-site publication has occurred within twelve (12) months after completion and close out of the Study, SITE may freely publish and disseminate the site-specific results of the Study, or otherwise publish or submit for publication an article, manuscript, abstract, report, poster, presentation, or other material containing or dealing with the site specific results of the Study (a "Publication") in accordance with the terms of this Agreement provided that, SITE shall: (i) obtain written consent of SPONSOR prior to any such Publication; (ii) provide SPONSOR with a copy of any proposed Publication sixty (60) days prior to submission for Publication. If SPONSOR determines that the proposed Publication contains patentable subject matter which requires



protection. SPONSOR may require the delay of publication for a further period of time not to exceed one hundred eighty (180) days for the purpose of filing patent applications.

- 6.4 Notwithstanding any other provision of this Section 6, and prior to any Publication, SITE shall preserve the right of SPONSOR to comment on the results and conclusions set forth in any proposed Publication upon SPONSOR's written request prior to the submission of any Publication. SITE agrees that all comments made by the SPONSOR in relation to a proposed Publication or presentation will be incorporated into the Publication or presentation. Reasonable comments for the purposes of this clause 6.4 shall mean such comments and suggestions that, with a view to the scientific interest or the treatment of Study subjects, will clarify or improve the proposed Publication or presentation of the results of the Study or the conclusions drawn therefrom, or any other such comments that aim to avoid a Publication or presentation that will misrepresent the results. SITE shall delete any SPONSOR's confidential information in the proposed Publication where reasonably requested by SPONSOR.
- 6.6 The obligations described in this Section shall survive the expiration or termination of the Agreement.

#### **ARTICLE 7: Confidentiality and Use Restrictions**

- 7.1 SPONSOR will disclose to SITE including its employees, agents, directors, and representatives, certain information furnished in any form, including written, verbal, visual, electronic or in any other media or manner, any information that a party would reasonably consider to be confidential or proprietary including, but not limited to, information concerning the Investigational Product, this Agreement, the Protocol, Study results, processes, know-how, discoveries, inventions, compilations, business or technical information, other materials prepared by either Party or their respective affiliates and representatives, containing or based in whole or in part, on any information furnished by the SPONSOR, and the procedures for carrying out the Study, (collectively, "**Confidential Information**"). SITE will keep, such Confidential Information in confidence and shall not use it for the benefit of nor disclose it to others, except as required by the Study or as defined in the Protocol and will at all times, refrain from any other acts or omissions that would reduce the value of SPONSOR's Confidential Information. SITE agrees to ensure that its employees, agents, contractors, representatives, or affiliates (including members of the Study team), who have access to Confidential Information are bound by an obligation of non-disclosure and shall procure non-disclosure agreements with such parties with the same breadth of coverage as provided for in this Section 7. SITE's obligations of confidentiality shall not apply to that part of the Confidential Information that SITE is able to demonstrate by documentary evidence: (i) already in the public domain prior to receipt of such information by SITE, or (ii) that becomes lawfully part of the public domain through no act on the part of the SITE, and/or its employees, agents, and representatives; or (iii) is obtained from a third party without an express obligation of confidence; or (iv) where required by applicable law, regulation, legal process, or other applicable judicial or governmental order to disclose, provided that, should the SITE be required to make such disclosure, where legally permissible, SITE shall provide the SPONSOR with prompt written notice of such request or requirement so that SPONSOR may, at its sole expense, seek an appropriate protective order prior to such disclosure; and where SITE is compelled to disclose, SITE



shall only disclose that portion of the Confidential Information that SITE is compelled to disclose and will exercise reasonable efforts to obtain assurance that confidential treatment will be accorded to that portion of the Confidential Information disclosed; or (v) is approved by SPONSOR with written authorization for disclosure by SITE.

- 7.2 SITE shall return all Confidential Information to SPONSOR, except where retention of same is required by Applicable Law, at the earlier of: (i) the time at which SITE ends its participation in the Study; (ii) as defined by the Protocol; or (iii) immediately upon request of SPONSOR.

#### **ARTICLE 8: Intellectual Property (IP)**

- 8.1 Intellectual Property that either Party owned prior to execution of this Agreement, or develops independently of the Study (without the use of SPONSOR IP and/or Confidential Information), is that Party's separate property and is therefore, not affected by this Agreement. Neither Party has any claims to, or rights in such intellectual property of the other Party.
- 8.2 The Parties agree that the SPONSOR owns the proprietary rights (whether or not protectable by patent, copyright or other intellectual property rights) to the Study and/or Study data or materials and other reports required to be generated and submitted to the SPONSOR pursuant to the Protocol, and any data compiled therein, or any discovery, concept, or idea arising out of the Study, including but not limited to any/all intellectual property and Confidential Information provided to SITE relating to the Study, or any inventions, mechanisms, substances, works, trade secrets, know-how, methods, or techniques (including improvements), tangible research products, any intellectual property conceived and reduced to practice, made or developed, the Investigational Product, formulation of the Investigational Product, device, or biologic, including its administration or use, alone or in combination with any other drug or device and any related assay or biomarker, or any improvements or methods of using such Investigational Product, existing or pending patents and patent applications, records or compilations of information (excluding records/compilations set forth in Section 8.3 herein), Study data produced by as a result of the Study, including records produced by Institution and/or Investigator, innovations of any kind made in performance or carrying out of the Study, and the Protocol, and the like, either of which, in whole or in part, relating to the Study, derived from the use or access to SPONSOR's Confidential Information, or developed conceived or reduced to practice during the course of conducting the Study (collectively, "SPONSOR IP"). The Parties agree that title, interest and rights to any SPONSOR IP shall remain the sole property of the SPONSOR. The Parties further agree that neither Party will have any proprietary or other ownership rights in any such SPONSOR IP, but that such rights in and to the following will remain with SPONSOR, subject only to the right of SITE, to use such information for: (i) Institution's own internal, non-commercial research and for educational purposes provided such use does not violate SPONSOR's confidentiality rights or impede commercialization; and (ii) if required during the Study, for the provision of standard of care medical treatment for a Study patient, without jeopardizing the SPONSOR's Intellectual Property Rights on such subject matter. This Agreement shall not be deemed or construed to convey or transfer any of such intellectual property rights to SITE except insofar as necessary to permit SITE to conduct the Study which is the subject of this Agreement. SPONSOR and SITE



acknowledge that the SPONSOR, owns the proprietary rights to the formulation of the Investigational Product, existing or pending patents and patent applications, trade secrets, know-how, and confidential information related to the Investigational Product and that these and all other proprietary rights shall remain the sole property of the SPONSOR.

- 8.3 Subject to the entirety of Section 7, and the provisions of this Section 8.1 and 8.2, Institution shall own all original hospital records, clinical and office charts, laboratory notes, evaluation checklists developed by Institution, pharmacy dispensing records, recorded data from automated instruments, copies or transcriptions certified after verification as being accurate copies, photographic negatives, microfilm or magnetic media, x-rays, subject files, and records kept at the pharmacy, at the laboratories involved in the Study (collectively, "**Source Documents**") provided that such does not utilize any Sponsor IP and/or contain any Confidential Information of Sponsor. Institution may utilize any Source Documents in any manner deemed appropriate by Institution without jeopardizing SPONSOR's Intellectual Property Rights derived out of such documents. Sponsor shall have the right to access such Source Documents in accords with Applicable Law.
- 8.4 Regulatory Filings. Any and all findings obtained as a result of the Study shall be communicated to SPONSOR, who shall be free to incorporate such findings in any regulatory filing concerning the Study. SITE understands and agrees that it shall have no ownership, license or access rights in, or to, such regulatory filings solely based upon the inclusion of such findings therein, nor shall they acquire any interest whatsoever in the findings as a result of performing the Study.
- 8.5 SITE shall promptly and fully disclose to SPONSOR, all discoveries and inventions (whether patentable or not) arising out of the performance of the Study or involving SPONSOR's IP ("**Study Inventions**"). SITE, each hereby assigns, all rights, title and interest in and to any Study Inventions and/or SPONSOR IP to SPONSOR. SITE hereby further agrees to refrain from taking any actions that would prejudice the intellectual property rights of SPONSOR in any way. Moreover, SITE agrees to inform the SPONSOR of any known infringement of its intellectual property rights, and to assist SPONSOR, at SPONSOR's sole expense, in actions intended to protect the SPONSOR's intellectual property rights.
- 8.6 Without SPONSOR's prior written approval, SITE, will not knowingly use in the Study, any of its own or any third-party intellectual property that may interfere with SPONSOR's rights to any SPONSOR IP and/or Study Inventions. Except as stated elsewhere in the Agreement, the Parties expressly authorize the use and grant a royalty-free license to their respective intellectual property to SPONSOR, to the extent necessary to accomplish the purposes of the Study.
- 8.7 SITE, agrees to use the Investigational Product only for a clinical Study under a regulatory authority Notice of Claimed Exemption for a New Drug as contemplated by this Agreement. SITE acknowledges that this Agreement constitutes a non-exclusive and non-transferrable or sub-licensable license to the SITE, by the SPONSOR to use the Investigational Product and the SPONSOR'S confidential and proprietary information relating to the Investigational Product solely for the research contemplated by this Agreement in accordance with the SPONSOR'S Protocol, and in accordance with regulatory authority regulations defining the



procedures, conditions and requirements applicable to investigational studies for new drugs under Applicable Law as amended from time to time, and any successor regulations. Furthermore, the SITE will not transfer the Investigational Product or related information to any third party, or otherwise make the Investigational Product or related information available to any investigator other than those listed in the SPONSOR'S Protocol, nor to any clinic or medical facility for use with subjects not properly enrolled in the investigational Study, and hereby acknowledges that the SITE shall not use or exploit the results of the Study for any purpose other than that contemplated by this Agreement.

- 8.8 **License.** If for any reason it is subsequently determined that SPONSOR is not the sole owner of any such SPONSOR IP or, with respect to any inventions and discoveries arising from research conducted under this Agreement, other than as expressly provided for herein ("**Other Inventions**"), SITE shall promptly disclose to SPONSOR on a confidential basis any Other Invention arising under this Agreement. SITE each individually, hereby grants SPONSOR an exclusive option, without fee, exercisable within ninety (90) calendar days following written notice of any Other Invention, to obtain an exclusive or nonexclusive, worldwide, royalty-bearing commercialization license, upon reasonable commercial terms and conditions (including measurable provisions for due diligence in development, commercialization and marketing), to all rights, title and interest that SITE, may have or obtain in any such Other Invention. This license will include the right to sublicense, make, have made, use, and sell the Other Invention or products incorporating the Other Invention. Upon SPONSOR's exercise of its option with regard to any Other Invention, Institution and SPONSOR will negotiate in good faith for up to eight (8) months ("**Negotiation Period**") in an attempt to reach a license agreement satisfactory to both parties. If an agreement is not reached by the end of the Negotiation Period, SPONSOR's rights to that Other Invention will expire, and Institution may license the Other Invention to third-parties without obligation to SPONSOR. If negotiations between SPONSOR and SITE terminate and SITE thereafter negotiates a license agreement with a third party on substantially better terms than those last offered to SPONSOR, SPONSOR shall be given the first right to refuse such terms for a period of one-hundred, eighty (180) days from the date of SPONSOR's receipt of a draft of such license agreement from Institution or Principal Investigator as the case may be. SITE, , each individually grants SPONSOR, for the term of the Negotiation Period, a non-exclusive, worldwide, royalty-free license on SITE's rights to the Other Invention for SPONSOR's internal research purposes

- 8.9 The obligations described in this Section shall survive the expiration or termination of the Agreement.

#### **ARTICLE 9: Use of Names**

- 9.1 Neither Party shall be permitted to use the name, trademark, trade name, logo, or any adaptation thereof, of the Sponsor and/or either Party hereto, in any news or publicity release, policy recommendation, advertisement, promotional material, promotional activity, or in any other commercial fashion, without the prior written consent of the other Party or where applicable, of SPONSOR subject, however, to the following:

- 9.1.1 Sponsor may, without prior consent, identify Principal Investigator as the person conducting the Study;



9.1.2 SPONSOR may disclose the Principal Investigator to investors or potential investors or as required by federal, state or local laws or security exchange regulations.

9.1.3 SITE may, without prior consent, disclose their participation in the Study (but only with respect to the indication, treatment period, and number of Study subjects enrolled) and may disclose SPONSOR as the source of funding for the Study as well as the Protocol title as necessary to comply with regulatory, academic, and governmental reporting requirements. SITE, will not issue and will ensure the Study staff will not issue, any information or statement to the press or public, including but not limited to advertisements for the enrolment of Study subjects, without, where appropriate, the review and prior written consent of SPONSOR.

9.2 Nothing in this Article 9 shall be construed as prohibiting SPONSOR from submitting reports with respect to the Study to a governmental agency as required by law.

#### **ARTICLE 10: Data Protection and Privacy**

10.1 SITE, shall undertake to insure:

10.1.1 that data obtained from the Study subjects in connection with the Study is utilized for no purposes other than as outlined in the Protocol and that SITE shall cause such data to be managed in accordance with Applicable Law;

10.1.2 compliance with Applicable Law on the protection of individuals with regard to the processing and free movement of personal data;

10.1.3 that all Study subjects are properly informed that the data collected from them may be considered personal data and to obtain from such Study subjects written consent to the processing, disclosure, and transfer of this data by SITE and SPONSOR;

10.1.4 to provide information as requested by SPONSOR, to authorize the processing and storage of certain personal identifying information and data concerning a Study patient and other site personnel involved in the Study for the purpose of fulfilling legitimate business requirements relating to the Study, meeting regulatory requirements, as well as for the purpose of evaluating SITE for inclusion in future studies; and

10.1.5 to obtain the consent of Study team members and all other personnel involved in the Study for the processing of their personal data as required by Applicable Law.

#### **ARTICLE 11: Subject Injury Reimbursement**

11.1 In accordance with Applicable laws, as amended from time to time, SPONSOR shall reimburse Institution for all reasonable and necessary medical expenses for the diagnosis, care and treatment of any injury to a Study patient directly resulting from Study patient's participating in the Study ("Subject Injury"); provided, however, that: (i) the Subject Injury or illness was not caused by Investigator/Institution's deviation from the Protocol, Applicable Law, or other written instructions provided by SPONSOR (except for medically necessary deviations); (ii) the Subject injury or illness was not caused by the negligence or misconduct of the SITE and/or SITE staff; (iii) the Subject injury or illness is not attributable to the natural progression of any underlying illness, any pre-existing abnormal medical



condition or underlying disease of the Study patient, or treatment that would have been provided to the Study patient in the ordinary course of treatment notwithstanding participation in the Study; (iv) the injury or illness was not covered by the Study patient's medical or hospital insurance, or any similar third-party payer providing such medical or hospital coverage; (v) the Subject injury or illness was not directly attributable to a failure of the SITE any of its personnel conducting the Study to adhere to the terms of the Protocol, directions of the SPONSOR, or Applicable Law pertaining to the administration of the Study; (vi) the injury or illness is not attributable to the Study patient's deviation from the reasonable direction of SITE, Study personnel or the Study patient's physician.

11.2 This provision shall survive the expiration of termination of this Agreement.

#### **ARTICLE 12: Termination**

12.1 Performance under this Agreement may be terminated by SPONSOR for any reason or no reason upon thirty (30) days written notice to SITE. Performance may be terminated upon thirty (30) days prior written notice by SITE if circumstances beyond its control preclude continuation of the Study. However, termination of this Agreement shall not relieve SITE of its obligations under Articles 5, 6, 7, 8 and 9 of this Agreement. Other than in cases of termination for breach of this Agreement by SPONSOR, SPONSOR shall make all payments due hereunder to SITE for actual costs, non-cancellable commitments incurred in the performance of the research, which have accrued up to the date of such termination, or, in case of a termination of this Agreement up to the date of receipt of such final rejection. Should Institution have received higher payments than the payments due according to the work already performed, Institution shall reimburse the balance to SPONSOR.

12.2 Performance under this Agreement may be terminated by SPONSOR or SITE immediately upon written notice without any further action or notice by either Parties, in the event (a) SITE ceases operations, is insolvent or unable to pay its debts when they become due; (b) of negligence or wilful misconduct by SITE or its employees, contractors or agents which impacts or reasonably may impact the Study; (c) SITE's breach of this Agreement, or obligation and/or warranty hereof; (d) for reasons related to Study patient safety as determined by SPONSOR; (e) the Principal Investigator ceases or is unable to serve and a successor acceptable to SPONSOR cannot assume his/her duties within a reasonable period of time; (f) in case any regulatory or legal authorization necessary for the conduct of the Study is finally rejected; (h) in the event that Principal Investigator becomes debarred, threatened with debarment or any similar proceeding, is excluded from being able to participate in any such Study, and/or utilizes the services of a third party directly or indirectly in order to perform obligations related to the activities under this Agreement that has been debarred, threatened with debarment or any similar like proceeding.

12.3 Except as otherwise provided above, where either Party fails to perform any of its material non-monetary obligations under this Agreement, and does not cure such breach within thirty (30) days of receipt of written notice of such default, then the non-defaulting Party, at its option, may terminate this Agreement by giving written notice of termination to the defaulting Party. In such event, this Agreement shall terminate on the date specified in such notice.



12.4 Upon completion, termination (early or otherwise), suspension or discontinuation of the Study or upon the request of SPONSOR; SITE will immediately stop screening and enrolling Study subjects, and subject to the protection of the safety and welfare of Study subjects, cease Study activities and complete its normal Study completion responsibilities in an orderly and safe manner, of which shall include but is not limited to: (i) cooperate promptly and diligently in an orderly and safe manner, in the wind down of the Study, including, without limitation, discontinuing the Investigational Product as soon as medically appropriate, allowing SPONSOR access to records and facilities for Study close-out procedures, requiring Investigator to complete any actions required by the role of Investigator, and transferring to SPONSOR all Study data and, if applicable, the administration and conduct of the Study; (ii) allowing SPONSOR access to records and facilities for Study close-out procedures, and requiring Investigator to complete any actions required by the role of Investigator; (iii) returning all unused supplies associated with the Study to SPONSOR or the appropriate facility with the exception of Investigational Product which shall be returned to SPONSOR; and (iv) Immediately delivering to the SPONSOR, all Confidential Information, except for copies to be retained in order to comply with Institution's archiving obligations or for evidential purposes.

#### **ARTICLE 13: Liability/Indemnification/Insurance**

13.1 **SPONSOR.** SPONSOR shall be liable for and agrees to indemnify and hold SITE harmless from and against, any and all any/all claims, damages, liabilities and losses (including reasonable attorney's fees and expenses) (collectively, "Losses") arising out of SPONSOR's negligent act, omission or wilful misconduct.

13.2 **Institution.** Institution shall be liable for, and agrees to indemnify and hold the SPONSOR harmless from and against, any and all Losses caused by or attributable to SITE's (including principal Investigator), and/or any of its affiliates, subsidiaries, employees (including sub-investigators), officers, directors, contractors, sub-contractors, consultants or agents (collectively, "Representative(s)"): (i) negligent acts, omissions, wilful or intentional and/or professional malfeasance or misconduct of any Representative(s) involved in the Study; (ii) actions by the any Representative that is contrary to this Agreement, the Protocol, or other written instructions provided to an Institution Representative(s) by SITE; (iii) any unauthorized warranties relayed by any such Representative(s) to a third party concerning the Study Drug; and/or (iv) the failure of Institution Representative(s) to obtain the appropriate informed consent.

**EXCEPT WITH RESPECT TO A PARTY'S INDEMNIFICATION OBLIGATIONS IN SECTIONS 13.1 AND 13.2, NEITHER PARTY SHALL BE LIABLE FOR ANY SPECIAL, INCIDENTAL, PUNITIVE, INDIRECT OR CONSEQUENTIAL DAMAGES OF ANY KIND, INCLUDING LOST PROFITS, WHETHER OR NOT A PARTY HAS BEEN ADVISED OF THE POSSIBILITY OF SUCH LOSS OR DAMAGE.**



13.3 **Insurance.** Institution represents that it will maintain general and professional liability insurance (malpractice) and if applicable, workers' compensation insurance, covering SITE's liability and the liability of its employees (including, Investigator and sub-investigator(s)) and its trustees, officers, agents, or directors, in amounts sufficient to adequately cover its obligations hereunder. Institution shall maintain such coverage for the duration of this Agreement and if the policy is claims-made, for two (2) years thereafter. Institution will provide evidence of all such coverage upon request. Institution will notify SPONSOR within twenty (20) days of any notice of cancellation, non-renewal, or material change in its insurance coverage.

13.4 The obligations described in this Section 13 shall survive the expiration or termination of the Agreement.

#### **ARTICLE 14: Miscellaneous**

##### **14.1 Assignment and Succession**

This Agreement and the rights and obligations hereunder granted to and undertaken by SPONSOR may be assigned by SPONSOR without prior written approval of SITE. Neither this Agreement, the obligations hereunder nor the rights granted to the SITE under this Agreement shall be assignable or otherwise transferable by the SITE without the prior written consent of SPONSOR. Any such assignee of the SITE shall be bound by the terms hereof as if such assignee were the original party hereto. Any assignment in violation of this provision shall be deemed null and void and of no effect.

This Agreement shall be binding upon and inure to the benefit of the Parties hereto, SPONSOR's assigns, successors, trustee(s) or receiver(s) in bankruptcy, and legal representatives and SITE'S permitted assigns, personal representatives, successors and trustee(s), or receiver(s) in bankruptcy. No assignment shall relieve either Party of the performance of any accrued obligation that such Party may then have under this Agreement.

##### **14.2 Independent Contractor Status**

In the performance of this Agreement the Principal Investigator and Institution shall be independent contractors with respect to SPONSOR. SITE is authorized to act as the agent for SPONSOR. SPONSOR shall not be bound by the acts of the SITE



#### 14.3 Notices

Any notices concerning the administration of this contract which are required or permitted by this contract shall be delivered by hand, sent by mail, or by facsimile to the following Party:

**To INSTITUTION at:**

Rev. Fr. Richard Aloysius Coelho

Address: Father Muller Charitable Institutions, Fr. Muller Road, Kankanady,  
Mangalore -575002, Karnataka.

Telephone: 0824-2238464

Attention : Director

**To PRINCIPAL INVESTIGATOR at:**

Dr. Jacintha Martis

Address : Professor, Department of Dermatology, Venereology and Leprosy, Father Muller  
Medical College Hospital, Fr. Muller Road, Kankanady,  
Mangalore -575002, Karnataka.

Telephone: 0824- 2238261

**To SPONSOR at:**

Clinical & Medical Operations, Clinical Management

Dr. Reddy's Laboratories Limited,

IPDO, New Admin Block, Bachupally

Telephone:

Attention: Head Clinical & Medical Operations

With a copy to:

Dr. Reddy's Laboratories, Limited

8-2-337, Road No. 3, Banjara Hills

Hyderabad, Telangana 500034 (INDIA)

Fax: +91 40 4900 2999

Attention: The General Counsel

Or to such other address for either Party as is subsequently specified in writing.

#### 14.4 Applicable Law and Dispute Resolution

This Agreement shall be governed in accordance with the laws of India. In the event the Parties are unable to mediate their dispute to a satisfactory resolution, the Parties agree that the dispute shall be exclusively settled by in accordance with the rules of arbitration under the Arbitration and Conciliation Act, 1996 as in effect on the Effective Date of this Agreement (the "**Arbitration Rules**"). The seat of arbitration will be Hyderabad, India. The language of the arbitration will be English. Each party will bear its own expenses in the arbitration and will share equally the costs of the arbitration; provided, however, that the arbitrators may, in their discretion, award costs and fees to the prevailing Party. Judgment upon the award may be entered in any court having jurisdiction over the award or over the applicable party or its assets.



#### 14.5 Impossibility and Waiver

In the event that any further lawful performance of this Agreement or any part thereof by any Party hereto shall be rendered impossible by or as a consequence of any law or administrative ruling of any government, or political sub-division thereof, having jurisdiction over such Party, such Party shall not be considered in default hereunder by reason of any failure to perform occasioned thereby.

No waiver of any term, provision or condition of this Agreement whether by conduct or otherwise in any one or more instances shall be deemed to be or construed as a further or continuing waiver of any such term, provision or condition, or of any other term, provision or condition of this Agreement.

#### 14.6 Amendment

14.6.1 New or additional Services, or amendments to the Services, must be agreed by the parties in writing and documented in writing ("**Change Order**").

14.6.2 SPONSOR may remove any existing agreed Services with at least 30 days' written notice to the SITE. Once notice has been properly given, the Agreement is deemed to be amended in accordance with that notice. If SPONSOR removes Services under this Article, SPONSOR will pay for reasonable substantiated costs actually incurred and/or that are non-cancellable at the date of removal, up to a maximum of the Fees that would otherwise have been payable.

14.6.3 The SITE acknowledges that, where the Study is part of a multi-site Study, SPONSOR's objective is to recruit a set number of Study Subjects across all Study sites. SPONSOR may, at its discretion, amend the number of Study Subjects required to be enrolled for participation in the Study, in order to achieve this objective. This may be reflected in a removal of or amendment to the Services.

14.6.4 Where the Services are amended in any way, the parties will agree on the changes, if any, to the Fees related to those Services which are required.

#### 14.7 Force Majeure

Any delays in or failure by either Party in performance of any obligations hereunder shall be excused if and to the extent caused by such occurrences beyond such party's reasonable control, including but not limited to acts of God, strikes, or other labour disturbances, war, whether declared or not, sabotage, and other causes, whether similar or dissimilar to those specified which cannot reasonably be controlled by the party who failed to perform.

#### 14.8 Conflict between Agreement and Protocol

If the event provision of this Agreement conflicts with a provision of the Protocol relating to the conduct of the Study, the Protocol shall take precedence on matters of medicine, science and Study conduct. This Agreement takes precedence in any other conflicts.



#### **14.9 Third Party Beneficiaries**

Notwithstanding any other provision in this Agreement to the contrary, the Parties agree that the SPONSOR is an intended third-party beneficiary of any Agreement(s) between the SITE and third parties and shall have the full right to enforce any and all obligations owned to it as through it were a party to those Agreements.

#### **14.10 Severability**

The provisions of this Agreement shall be deemed severable. Therefore, if any part of this Agreement is rendered void, invalid or unenforceable; such rendering shall not affect the validity and enforceability of the remainder of this Agreement unless the part or parts which are void, invalid or unenforceable as aforesaid shall substantially impair the value of the whole agreement to either Party.

#### **14.11 Integration and Amendment**

This Agreement sets forth the entire agreement between the Parties and merges all prior communications relating to the subject matter contained herein and may not be modified, amended or discharged except as expressly stated in this Agreement or by a written agreement signed by the Parties hereto.

#### **14.12 Warranties**

SITE, for itself and its officers and directors, warrant and represent that they: (a) possess the necessary resources, skills, expertise, equipment and infrastructure, and training to perform the Study professionally and competently; (b) are familiar with current Applicable Law and regulations related to the Study, and maintain a program for regularly updating their familiarity and compliance with such Applicable Law and regulations; (c) are licensed and in good standing with all necessary and appropriate government agencies; (d) have never been disciplined or debarred by any government agency; (e) have never been convicted of an offence which prohibits them from performing the Study; (f) are not currently the subject of any regulatory, civil or criminal investigation; and (g) shall maintain and provide evidence upon request comprehensive general liability insurance, professional liability insurance and worker's compensation insurance.

#### **14.13 Third Party Beneficiary**

The Parties acknowledge and agree that SPONSOR is an express, intended third party beneficiary of any Agreements SITE will enter for the purpose of this Agreement.

#### **14.14 Counterparts**



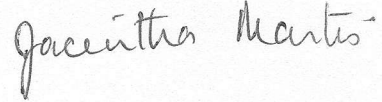

This Agreement may be executed in any number of counterparts, each of which counterparts, when so executed and delivered, shall be deemed to be an original, and all of which counterparts, taken together, shall constitute one and the same instrument. Facsimile and PDF signatures shall be treated as original signatures.



#### 14.15 Headings

Headings are used in this Agreement for convenience only and shall not affect any construction or interpretation of this Agreement.

IN WITNESS WHEREOF, the Parties hereto have caused this Agreement to be executed in duplicate as of the date and year first above written.

For <b>DR. REDDY'S</b> <b>LABORATORIES LIMITED,</b>  	For <b>FATHER MULLER</b> <b>CHARITABLE INSTITUTIONS</b>  	For <b>PRINCIPAL</b> <b>INVESTIGATOR,</b>  
<b>Authorised Signatory</b>	<b>Authorised Signatory</b>	<b>Authorised Signatory</b>
Name: Dr Ramesh Jagannathan	Name: Rev. Fr. Richard Aloysius Coelho	Name: Dr. Jacintha Martis
Designation: Director & Head	Designation: Director	Designation: Professor
Place: Hyderabad	Place: Mangalore	Place: Mangalore
Department: Clinical Development	Institution: Father Muller Charitable Institutions, Fr. Muller Road, Kankanady, Mangalore - 575002	Department: Dermatology, Venereology and Leprosy, Father Muller Medical College Hospital, Fr. Muller Road, Kankanady, Mangalore - 575002
<b>Witness</b>		
Name:		
Designation:		
<b>Finance</b>		
Name:		
Designation:		
<b>Legal</b>		
		



**ANNEXURE -1**  
**STUDY**

1. Title :A Clinical Trial Study to evaluate "A Phase 2, Multicenter, Randomized, Double blind, Comparative Study to evaluate the reduction in incidence of scarring in acne vulgaris subjects treated with combination of Benzoyl peroxide (2.5%/5%), Zinc oxide and Polysiloxanes compared to Benzoyl Peroxide (2.5%/ 5%)".
2. Key information about the Study

**Primary & Secondary Objective:** To evaluate the safety and efficacy of Lorcaserin in comparison to placebo in the treatment of Obesity.

*Study Name:* Benzoyl peroxide (2.5%/5%), Zinc oxide and Polysiloxanes

*Protocol Number:* DRL-INDG04-BPO/2016

**3. Study Fees**

**PAYMENT TERMS AND SCHEDULE**

**1. Estimated Expenses for 20<sup>#</sup> completed patients\***

Sr. No	Particulars	Unit Costs (In INR)	No. of patients	No. of visit/months	Total Amount (in INR)
1	Investigator Consultancy Charges	Rs 1500	20	8	240000
2	Research Assistant Charges	Rs 12000	-	10 months	120000
3	Photographic Evaluation	Rs 300	20	8	48000
4	Patient Conveyance	Rs 500	20	8	80000
5	Screening Failure Charges (Assuming SF@ 05 patients) Consultation Charges	Rs 1500	05	-	7500
6	Fax, Telephone, Stationery, Courier	Rs 1000		10 months	10000
9	Institutional overhead charge (15 % from Sr. No 1& 2)				54000
10	<b>Total Cost of the Project for the 20<sup>***</sup> completed Patients</b>				<b>559500</b>

**2. Payment Schedule:**

The agreed payment schedule is as follows.

Instalment	Milestone of Payment
1 <sup>st</sup>	15% of estimated total as Advance payment
2 <sup>nd</sup>	15% of estimated total after 5 patients are enrolled.
3 <sup>rd</sup>	15% of estimated total after 10 patients are enrolled.
4 <sup>th</sup>	15% of estimated total after 20 patients are enrolled.
Balance amount	On receipt of last completed case record form.

The final balance amount payable will be calculated on the basis of the actual number of patients who complete the Clinical trial

\*The dropouts will be paid at actuals for Investigator Consultation charges, Patient Conveyance and Photographic charges upto the point of dropout.

\*\* Research Assistant will be paid a fixed amount, whereas the investigators will be paid compensation per patient/per visit

\*\*\* If there are less number of patients enrolled in the study, payment will be made paid according to prorata basis.

# In case extra patients (more than 20 patients) are recruited in this clinical trial at the request of sponsor, additional payment will be made on pro rata basis for Investigator Consultation charges, Photographic charges and Patient Conveyance (as applicable).

@ Screening failures will be paid at actuals for one time consultation charges.

3.	If Any amendment in the protocol or any other documents which require Responsible Ethics Committee approval it will be charged as additional cost;
4.	In the event of pre-termination/closeout of the project, professional fees will be paid based on the milestone achieved up to the termination with pro-rata adjustment;
5.	Services tax and VAT will be charged additionally as per the prevailing rates;
6.	Any government approvals/Notification required for the study other than EC approvals shall be obtained by the Dr. Reddy's Laboratories Ltd. Limited.;

Please provide the following details for future payments:

1. Cheques should be issued in favour of **"Father Muller Research Centre"**
2. Name of the bank: Syndicate Bank
3. Branch: Father Muller Charitable Institution Branch, Mangalore
4. Bank Account No.:02392160000136

Statutory Details:

PAN No.AAATF0345D(Scan/ Xerox copy of Pan Card to be enclosed)



## MEMORANDUM OF UNDERSTANDING

This Memorandum of Understanding (herein after referred to as "MOU") is made and executed on this date **December 1, 2017** at Mangalore

### BY AND BETWEEN

Father Muller Medical College Hospital, Mangalore (a unit of Father Muller Charitable Institutions) situated at Father Muller Road, Kankanady, Mangalore - 575002 represented by Rev Fr. Rudolph Ravi D'sa, Administrator (hereinafter referred to as "FMMCH") which term unless repugnant to the context thereof, shall mean and include its successors-in-interest and permitted assigns, of the FIRST PART

### AND

Metropolis Health care ltd. having its office at A J Hospital and Research Center Kuntikana, Mangalore, D.K- 575008 duly represented by Dr. Krishna Prasad HV, Chief of Lab Services and Consultant Pathologist (Hereinafter referred to as "METROPOLIS") which term unless repugnant to the context shall mean and include its successors and permitted assigns) of the SECOND PART

"FMMCH" and "METROPOLIS" are individually and collectively referred to as "Party" and "Parties" respectively.

### WHEREAS

1. Father Muller Medical College Hospital Laboratory, a division of Father Muller Medical College Hospital is a clinical laboratory delivering specialized testing facilities in the field of Biochemistry, Hematology, Histopathology and Microbiology.
2. FMMCH offers Inter Laboratory Quality Control specialized pathological diagnostic services on a per-request basis from similar health care facilities.
3. KSHEMA owns and operates a hospital, requires services of the type offered by FMMCH.
4. KSHEMA desires to obtain services from FMMCH and FMMCH is willing to provide such services to METROPOLIS, in accordance with the terms and conditions set forth within.

Wherefore, it is agreed between the Parties as under:

#### 1. Term

- 1.1 This agreement shall be a valid for a period of two years from the date of execution of this agreement. This agreement shall come into effect from December 1, 2017. However either party will renew this agreement for further period of one year with mutual consent.

#### 2. Objective

- 2.1 The objective of this MOU is to establish a written document framing a basic understanding under which both the parties shall be governed for conducting diagnostics and monitoring tests on the samples received by METROPOLIS.

#### 3. Scope of Work

- 3.1 During the term hereof or the extended term as the case may be FMMCH shall provide the services to METROPOLIS for all the tests requested by METROPOLIS. The list of tests annexed to this agreement as Annexure 1.

**4. Role and Responsibilities of Father Muller Medical College Hospital**

4.1 FMMCH shall conduct tests/investigations as per duly filled request form filled by METROPOLIS. The testing and reporting shall be carried out conforming to prevalent high standards of quality.

4.2 FMMCH shall provide reports of tests/ investigations through hard copy by courier.

4.3 FMMCH shall conduct tests/investigations on the basis of samples received from METROPOLIS. The sample received from METROPOLIS shall be tested and reported within two or three working days under normal circumstances. Reporting timeliness will be in accordance with prevalent quality standards.

**5. Roles and Responsibilities of METROPOLIS**

5.1 METROPOLIS shall be responsible for proper packing of samples and transportation in defined condition and temperature. Hospital will not be responsible for packing and transportation.

5.2 METROPOLIS shall be responsible for sending duly filled test requisition form, patient history, samples packing and labeling at required temperature in good condition to FMMCH for test/ investigations.

5.3 METROPOLIS shall make payments to FMMCH for services provided under this MOU within 15 days of receiving the invoices.

5.4 It is the responsibility of METROPOLIS to provide additional details requested by FMMCH to conduct the test/ investigation.

**6. Force Majeure**

6.1 Any delay in reporting the test/ investigation shall be subject to Force Majeure, such as unavailability of test kits, failure of test, incomplete patient / test details, problem sample, need for repeat sample/ testing, instrument or machinery breakdown, civil unrest, riots, change in or in the interpretation of laws, strikes, lockout or other labour problems, unavailability of supply, fire or explosion, act of terrorism and other natural calamities. FMMCH would make efforts to mitigate the impact of such Force Majeure conditions and ensure timely testing as feasible and inform METROPOLIS accordingly.

**7. Consideration:**

7.1 The billing shall be done on monthly basis starting from 1<sup>st</sup> to 31<sup>st</sup> of each month and METROPOLIS undertakes to clear all the outstanding payments within 15 days from the date of receiving the invoices.

7.2 Revision of tariff by FMMCH will be intimated to METROPOLIS in writing, upon which the revised rate tariff shall be applicable from the date revision.

**8. Termination and Consequences of Termination**

8.1 Each of the parties makes the following representations and warranties to the other party hereto that the representing party has the full power and unrestricted authority to enter into this MOU. Entering this MOU and performing the obligations hereunder does not conflict with and is not prohibited under the terms of any other agreement, document, law, rule, regulation or court order to which the representing party is subject. Each of the parties has the full power and unrestricted authority to grant the licenses that are granted herein.

**9. Termination and Consequences of Termination**

9.1 This MOU may be terminated on mutual consent or by either party with at least 30 days prior written notice without assigning any reasons.

9.2 All payments due, becoming due and payable to the Parties as on the date of termination, under the terms of this MOU shall continue to be due and payable to the Parties notwithstanding the termination hereof.

**10. Confidentiality:**

10.1 Each Party shall keep secret all Confidential Information, if any, transmitted to it or made available to it by the other Party and shall not pass such Confidential



Information on, wholly or partly, to third parties without express written consent of the other Party.

10.2 The Parties shall not disclose the terms of this MOU or make any announcement in respect of the subject matter thereof without prior written consent of the other Party unless the disclosure is required by law or other regulatory authorities. In the event disclosure is required by law, rules or regulations, such disclosure shall be made after obtaining written permission of other party.

10.3 The Confidentiality obligations in this do not apply to disclose information that either Party in writing can prove that:

- i. It was known at the time of disclosure to be free of any obligation to keep it confidential, as evidenced by written records.
- ii. Became generally publicly known through authorized disclosure.
- iii. The information was independently developed without access to or use of any confidential information, as evidenced by written records, or
- iv. The information was rightfully obtained from a third party who had the right to transfer or disclose it without violation of any confidentiality obligations.

#### **11. Dispute Resolution and Governing Law**

11.1 In case if any difference or dispute arises between the Parties herein, the Parties shall hold mutual discussions to resolve such difference and / or dispute in an amicable manner for the best interests of both Parties. Parties shall try to resolve the difference and / or dispute within 30 days or such extended time as agreed between the Parties. In case, any difference and / or dispute could not be resolved through mutual discussion then such difference and / or dispute between the Parties shall be referred to sole arbitrator appointed by both the parties in accordance with the Arbitration and Conciliation Act, 1996. The venue of the arbitration shall be Mangalore. The award of the arbitration shall be final and binding between the Parties.

#### **12. Limitation of Liability**

12.1 To the fullest extent permitted by Applicable Law neither Party nor its affiliates shall be liable for any special, indirect, consequential, or incidental damages (including but not limited to damages for loss of business profits, business interruption, loss of business information, and the like) arising out of this MOU even if either Party has been advised of the possibility of such damages.

#### **13. Miscellaneous:**

Relationship: No provision of this MOU shall be deemed to constitute a partnership or joint venture between the Parties.

Further, each Party shall inform its employees that they shall not be treated as employees of the other Party for any purpose whatsoever and that they shall not exercise any rights or seek or be entitled to any benefits accruing to the regular employees of the other Party.

No provision of this MOU shall constitute either Party as the legal representative or agent of the other, nor shall either Party have the right or authority to assume, create or incur any liability or any obligation of any kind, express or implied, against or in the name of or on behalf of the other Party except as provided expressly under this Agreement.

**Notices:**


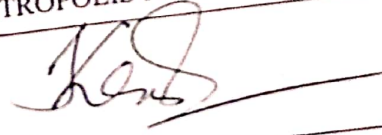
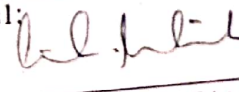



Any notice required or permitted to be given hereunder shall be in writing and shall be effectively served.  
 13.1.1 If delivered personally, upon receipt by the other party;  
 13.1.2 If sent by prepaid courier service, airmail or registered mail, within seven(7) days of being sent; or

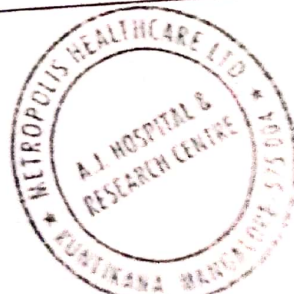
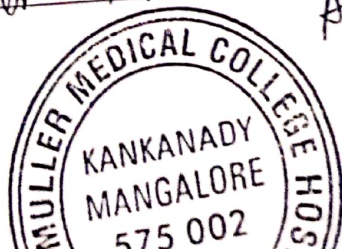
13.1.3 If sent by facsimile or other similar means of electronic communication (with confirmed receipt), upon receipt of transmission notice by the sender.  
 13.1.4 Any notice required or permitted to be given hereunder shall be addressed as given in the title to this MOU.  
 13.1.5 Any party hereto may change any particulars of its address for notice, by notice to the other in the manner aforesaid.

**Violation of terms:**

The Parties agree that each party shall be entitled to an injunction, restraining order, right for recovery, suit for specific performance, or such other equitable relief as a court of competent jurisdiction may deem necessary or appropriate to restrain the other party from permitting any violation or enforce the performance of the covenants, obligations and representations contained in this MOU. These injunctive remedies are cumulative and are in addition to any other rights and remedies the Parties may have at law or in equity, including without limitation, a right for recovery of the amounts due under this Agreement and related costs and a right for damages.

IN WITNESS THEREOF the Parties have through their respectively duly authorized representatives, executed this MOU the day, month and year first hereinabove written.

Signed and delivered by FMMCH	Signed and delivered by
Father Muller Medical College Hospital	METROPOLIS
	
(Sign)	(Sign)
By: Rev Fr. Rudolph Ravi D'sa	By: Dr. Krishna Prasad HV
Title: Administrator	Title: Chief of Lab Services and Consultant Pathologist
Witness 1:	Witness 1:
	
(Sign)	(Sign)
Name: MRS. LIDIA PAN	Name: Mr. Danil Pais
Witness 2:	Witness 2:
	
(Sign)	(Sign)
Name: SHIVASHANKARA	Name: Pooja R. Shenoy





To:- oph th alms dny Dept



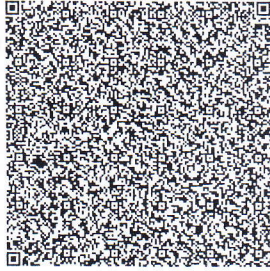
सत्यमेव जयते

# INDIA NON JUDICIAL Government of Karnataka

## e-Stamp

Certificate No. : IN-KA11122819045680P  
Certificate Issued Date : 01-Apr-2017 11:02 AM  
Account Reference : NONACC (FI)/ kaksfcl08/ KANKANADY/ KA-DK  
Unique Doc. Reference : SUBIN-KAKAKSFCL0870888458933235P  
Purchased by : FR MULLER MEDICAL COLLEGE HOSPITAL  
Description of Document : Article 12 Bond  
Description : MOU  
Consideration Price (Rs.) : 0  
(Zero)  
First Party : FR MULLER MEDICAL COLLEGE HOSPITAL  
Second Party : DISTRICT HEALTH AND FAMILY WELFARE SOCIETY  
Stamp Duty Paid By : FR MULLER MEDICAL COLLEGE HOSPITAL  
Stamp Duty Amount(Rs.) : 100  
(One Hundred only)

Director FmCT  
(FmCT)



Please write or type below this line.....

## MEMORANDUM OF UNDERSTANDING (MOU) BETWEEN DISTRICT HEALTH AND FAMILY WELFARE SOCIETY (R) (BLINDNESS CONTROL DIVISION) AND PARTICIPATING NON GOVERNMENT ORGANIZATION

### 1. Preamble :

1.1. WHEREAS the Union Cabinet has approved continuation of National Program for Control of Blindness, hereafter referred to as NPCB, for implementation in all the States of the Country during the 11<sup>th</sup> Plan (2007-2012);

In-charge Director

Father Muller Charitable Institutions  
Kankanady, Mangalore - 575 002

### Statutory Alert:

1. The authenticity of this Stamp Certificate should be verified at "www.shcilestamp.com". Any discrepancy in the details on this Certificate and as available on the website renders it invalid.
2. The onus of checking the legitimacy is on the users of the certificate.
3. In case of any discrepancy please inform the Competent Authority.



- 1.2. WHEREAS the Cabinet has also agreed to follow the strategies of "Vision 2020 : The Right to Sight" in NPCB as per Plan of Action developed for the country.
- 1.3. WHEREAS NPCB aims to reduce prevalence of blindness by implementing various activities through State and District Blindness Control Societies established in all the districts of the country;
- 1.4. Whereas the NPCB seeks to involve eye care facilities in Government, Non-Government and Private sectors having capacity to perform various activities under National Programme for Control of Blindness;
- 1.5. AND WHEREAS schemes for Non-Government Organizations (hereafter referred as NGO) providing eye care services are implemented as per pattern of assistance approved by the Cabinet;
- 1.6. NOW THEREFORE the signatories of Memorandum of Understanding (MOU) have agreed as set out herein below :

## 2. Parties of MOU :

This MOU is an agreement between District Health and Family Welfare Society (R.) (Blindness Control Division) of Dakshina Kannada of the State of Karnataka; hereafter called District Health and Family Welfare Society (R.) (Blindness Control Division) and Father Muller Charitable Institutions.

## 3. Duration of MOU :

This MOU will be operative from the date of its signing by the parties and remain in force till **31<sup>st</sup> March 2018**. MOU can be renewed through mutual agreement by the parties.

## 4. Commitments of NGO :

Through this MOU the NGO agrees to provide following services under National Programme for Control of Blindness :

Sl.No.	Activities	Yes / No
a)	Screening of population in all the villages / townships in the area allotted to the NGO and preparation of village wise blind registers.	Yes
b)	Identification of cases fit for cataract surgery, motivation thereof and transportation to the base hospital	Yes
c)	Pre-operative examination and investigation as required	Yes
d)	Performance of cataract surgery preferably IOL implantation through ECCE / IOL, Small Incision Cataract Surgery (SICS) or Phaco-emulsification of patients identified in allotted areas, self motivated walk-in cases and those referred by DH &FWS (BCD)	Yes

*[Signature]*



e)	Post-operative care including management of complications, if any and post-operative counseling regarding use of glasses;	Yes
f)	Follow-up services including refraction and provision of glasses, if required providing best possible correction.	Yes
g)	Submission of cataract surgery records of operated cases.	Yes
h)	Eye operation for poor and deserving patients other than cataract surgery	Yes

**5. Commitments of District Health and Family Welfare Society (Blindness Control Division) :**

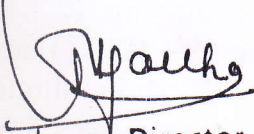
Through this MOU, the DH & FWS (BCD) agrees to provide following support to participating NGO to facilitate service delivery :

Clause	Clause of Agreement	Yes / No
5.1	Issue Certificate of Recognition about participation in NPCB	
5.2	Undertake random verification of operated cases not exceeding 5% before discharge of patients;	
5.3	Sanction cost of free cataract operations performed by the NGO as per GOI guidelines indicated in para 6 below within one month of submission of claim along with Cataract Surgery Records;	
5.4	Make payment of the sanctioned amount to the NGO on monthly/quarterly basis;	
5.5	Regularly disseminate literature, guidelines or any other relevant information to participating NGO)	

**6. Grant-in-aid to NGO for this scheme is governed by the following table :**

(Rupees per operation)

	Items	ECCE/IOL	SICS/PHACO
a.	Drugs and consumables	250	250
b.	Sutures	100	0
c.	Spectacles	125	125
d.	Transport/POL	150	150
e.	Organization & Publicity	125	125
f.	IOL, Viscoelastics & additional Consumables	250	350
	<b>Total</b>	<b>1000</b>	<b>1000</b>

  
 In-charge Director  
 Father Muller Charitable Institutions  
 Kankanady, Mangalore - 575 002

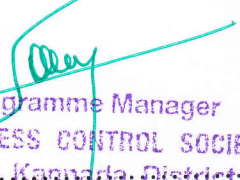
**7. Grant-in-aid to NGO for the Scheme other than Cataract Surgery :**

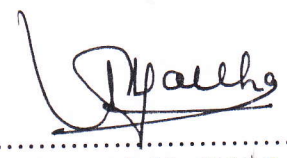
1.	Diabetic Retinopathy	Rs.1,500.00
2.	Glaucoma	Rs.1,500.00
3..	Keratoplasty	Rs.5,000.00
4.	Squint	Rs.1,500.00
5.	Retinopathy of Prematurity	Rs.5,000.00
6.	Retinoblastoma	Rs.1,000.00
7.	Congenital Ptosis	Rs.1,000.00
8.	Intraocular Trauma in children	Rs.1,000.00
9.	Low vision	Rs. 500.00

**8. Termination of MOU :**

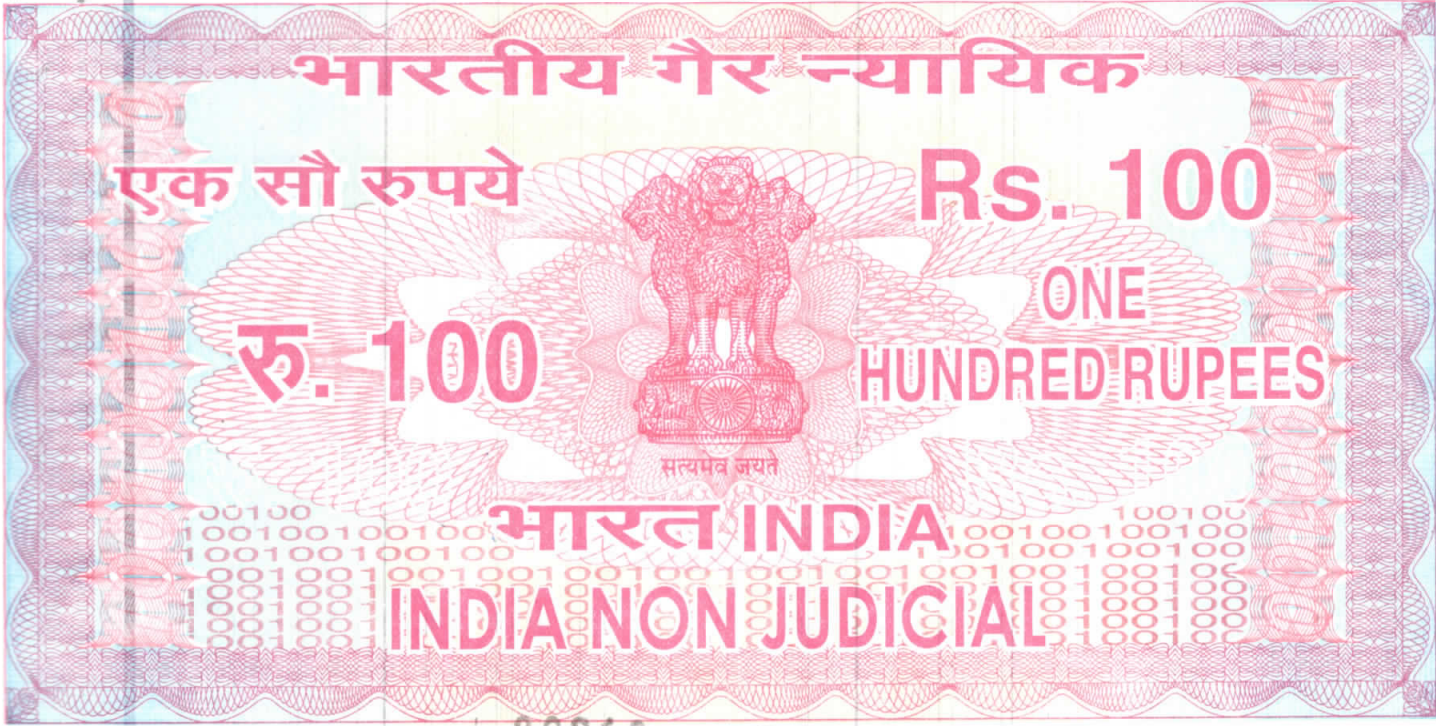
Commitments agreed to by the Parties are meant for prevention and control of blindness and therefore MOU should generally not be suspended or terminated. However, both parties can decide to suspend or terminate the MOU.

Signed this day, the 1<sup>st</sup> of April 2017.

  
 Dist. Programme Manager  
 DIST. BLINDNESS CONTROL SOCIETY  
 Dakshina Kannada District  
 For and on behalf of  
 District Health and Family Welfare Society (BCD)

  
 For and on behalf of NGO  
 In-charge Director  
 Father Muller Charitable Institutions  
 Kankanady, Mangalore - 575002





गुजरात गुजरात GUJARAT

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तारीख : 8  
नाम : CLIANTHA Research Limited  
Opp. Pushparaj Towers,  
Nr. Judges Bungalows,  
Bodakdev, Ahmedabad-380054.  
Ph.: +91 - 79 - 26853088-92  
फै. 88219  
ला. नं. ओ.स.पी. 88219  
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वे.नं.स.पी. 88219

## CLINICAL TRIAL AGREEMENT

### PROTOCOL CRL111735

This Clinical Trial Agreement (the "Agreement") is effective on the date fully executed by the parties (the "Effective Date") and entered into by and between

**CLIANTHA RESEARCH LIMITED**, a part of Cliantha Group, a company incorporated under the Companies Act, 1956 having its Registered Office at Commerce House II, Opp. Pushpraj Towers, Near Judges Bungalows, Bodakdev, Ahmedabad-380 054, India (hereinafter referred to as "CRO" which expression, unless repugnant to the context or meaning thereof shall mean and include its affiliates, employees, assignees, subsidiaries, nominees, agents and successors-in-interest)

AND

Confidential

CRL111735 Study

Page 1 of 25



**Dr. Ramesh Bhat M.** whose principal place of business is **Father Muller Medical College & Hospital, Father Muller Road , Kankanady , Mangalore 575002, Karnataka, India**

(hereinafter referred to as the "**Principal Investigator**" which expression, unless repugnant to the subject or context therein, shall mean and include his legal heirs, administrators, executors and assigns)

**AND**

**Father Muller Charitable Institutions, Father Muller Road , Kankanady , Mangalore 575002, Karnataka, India** (hereinafter referred to as the "**Institute**" which expression, unless repugnant to the subject or context therein, shall mean and include its authorized representative(s), administrators, executors, assigns & successors-in-interest)

**CRO, Principal Investigator and Institute** are referred to herein individually as a "Party" and collectively as "Parties".

Whereas, **Morningside Healthcare Ltd**, Morningside House, Unit C, Harcourt Way, Meridian Business Park, Leicester, LE19 1WP, UK, Tel# +44116045950

(Hereinafter referred to as the "**Sponsor**") through its Agent CRO desires the Institution to study Drug Address

and the Institution is willing to perform a clinical study of the Study Drug (defined herein below); and

WHEREAS, the Study (defined below) is of mutual interest and benefit to the Sponsor, CRO, Institution and Principal Investigator and will further the investigational and research objectives of the Institution and Principal Investigator;

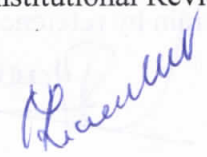
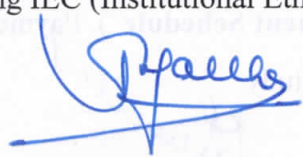
WHEREAS, the Principal Investigator and the Institution have the **qualified personnel and the facilities** equipped according to Good Clinical Practices (GCP) to undertake the Study (defined herein below);

NOW, THEREFORE, in consideration of the promises and mutual covenants herein contained, the Parties agree as follows:

**1. THE STUDY AND THE PROTOCOL**

**The study of Clindamycin Phosphate 10 mg/g + Benzoyl Peroxide 50 mg/g Gel (Morningside Healthcare Ltd, UK) (the "Study Drug") shall be conducted, under the direction of the Principal Investigator, in the treatment of patients ("Subjects") in accordance with this Agreement and the protocol identified as Protocol ID No. CRL111735 and entitled "A Randomised, Double-blind, Multicentre, Parallel-group, Active & Placebo Controlled, Three Arm Clinical Study to Compare the Efficacy and Safety of Clindamycin Phosphate 10 mg/g + Benzoyl Peroxide 50 mg/g Gel (Morningside Healthcare Ltd, UK) versus DUAC® Once Daily 10 mg/g + 50 mg/g Gel (GlaxoSmithKline UK Limited) in Subjects with Acne Vulgaris."** A copy of which is attached hereto as Exhibit A (the "**Protocol**"), including any subsequent duly authorized amendments, and which is hereby incorporated by reference (the "**Study**"). The Study will be monitored on behalf of the Sponsor by the CRO.

Institution's obligation to conduct the Study is expressly conditioned upon the approval of the Protocol by an IEC/IRB that complies with the requirements of Drug Controller General of India and Schedule Y and applicable regulatory requirements. Sponsor, Principal Investigator and Institution shall cooperate in preparing and filing the Protocol, Informed Consent Form and other information with the reviewing IEC (Institutional Ethics Committee) or IRB (Institutional Review Board).





## 2. THE STUDY SCHEDULE

- A. **Study Initiation.** All contractual and regulatory documentation must be received by Sponsor and CRO before the initiation of the Study. The Principal Investigator shall initiate the Study at the earliest after receiving the applicable regulatory / IEC / IRB approvals.
- B. **Enrollment.** Principal Investigator will enroll atleast 40 to 50 (as per the randomization schedule) and **not more than 100 Subjects** (as per the randomization schedule) (the "Site Maximum") for the duration of enrollment. The Principal Investigator shall commence enrollment of the Subjects once all the contractual and regulatory obligations have been met. Enrollment of, and payment for, each Subject over the Site Maximum shall require prior written consent of the Sponsor. Notwithstanding the foregoing, the Institution immediately shall cease enrolling the Subjects upon receipt of notice from the Sponsor, or the Sponsor's designee, that, in the sole determination of the Sponsor:
- i. the Complete Study enrollment has been achieved; or
  - ii. the Sponsor has placed the Study on hold, for any reason; or
  - iii. the Study has been placed on hold by the DCGI or applicable regulatory agency for any reason.
- C. **Study Documentation.** Case Report Forms ("CRFs") must be satisfactorily completed maximum within **three (3) days** of each Subject visit. If any tests are to be performed after the Subject visit, CRF shall be completed maximum within **three (3) days** of receipt of test results for each Subject, provided, however, that with respect to the last Subject enrolled at the Site, CRF for such Subject must be completed within **three (3) days** of such Subject's last visit to the Site. The Principal Investigator shall ensure the accuracy, completeness, legibility and timeliness of the data reported to the Sponsor in the CRFs and in all required reports. Safety data (Serious Adverse Event Report Forms) will be faxed / mailed to Sponsor and CRO within **twenty four (24) hours** of (i) the Subjects visit and (ii) receipt of the test results at, or from which, such event was reported, noted or recognized. Data Clarification Forms Queries ("DCFs") must be resolved within **two (2) days** of its receipt.
- D. **Subject Samples.** All biological samples collected from the Subjects shall be prepared and shipped in accordance with appropriate reference of the Protocol / Study requirements / Study manuals.
- E. **Study Completion.** The Institution shall complete the enrollment of all the Subjects within the specified timeline given or informed by the Sponsor/ CRO. The Institution shall input all final CRF data and complete the final CRFs not later than three days after the last Subject visit.

## 3. PAYMENT

- A. **Budget and Payment Schedule:** CRO shall on behalf of the Sponsor reimburse the Institution all direct and indirect costs incurred by the Institution in accordance with the Budget and Payment Schedule, attached hereto as Exhibit B and incorporated herein by reference (the "**Budget and Payment Schedule**"). Payment shall be made by



cheque payable to **Payee Name: Father Muller Research Centre (PAN No: AAATFO345D)**. Payment shall be made within thirty (30) days after CRO has received invoice from the Principal Investigator. In addition, CRO shall reimburse directly the IEC / IRB for all costs associated with the Study.

- B. Payment of Costs Outside Budget and Payment Schedule.** Payment for any costs not specifically described in the Budget and Payment Schedule must be approved in advance in writing by the CRO's Project Manager.
- C. Payment Terms.** CRO shall have no obligation to make payments for any subject who is not qualified to participate in the protocol based on the inclusion and exclusion criteria described in the protocol. Queries pertaining to a subject's eligibility shall be addressed to and resolved by the sponsor's clinical and/or medical monitor identified in the protocol prior to entry of any such subject into the study.

The foregoing notwithstanding:

Upon submission of such documentation as may be requested, to the extent not already paid by CRO, CRO will pay the actual cost of completed visits in accordance with the Budget and Payment Schedule for the Subjects who are dropped from the Study or withdraw from the Study; provided, however, such costs were incurred at a time when, in the good faith judgment of CRO, none of the Institution, its employees or agents, or the Principal Investigator knew or could have reasonably determined that such Subject was not or would not be an Eligible and Evaluable Subject. **"Eligible and Evaluable Subjects"** are defined as Subjects who have satisfied all the Protocol requirements, including compliance with dosing regimen and visit schedule, and are eligible to be included in the statistical analysis for the Study; and Institution and Principal Investigator agree that all payments made under this Section are made solely for the performance of activities relating to the Study and for no other purpose.

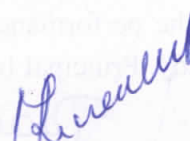
- D. Payment Recipient and Mailing Address.** All cheques/online transfer shall be made payable to the entity / person mentioned in the Clause 3A.

The mailing address for checks shall be:

**Address:**

**Dr. Ramesh Bhat M.**

Department of Dermatology Venereology and Leprosy,  
Father Muller Medical College & Hospital,  
Father Muller Road , Kankanady ,  
Mangalore 575002, Karnataka, India





The further details for the payments should be provided as

<b>Cheque in the favor of</b>	<b>Father Muller Research Centre payable at Mangalore</b>
<b>PAN Number</b>	<b>AAATF0345D</b>
<b>Name of Bank</b>	<b>Syndicate Bank</b>
<b>Branch</b>	<b>Father Muller Charitable Institution Branch, Mangalore</b>
<b>Account No.</b>	<b>02392160000136</b>
<b>Branch Code</b>	<b>0239</b>
<b>IFSC Code</b>	<b>SYNB0000239</b>

- E. Reimbursement.** Upon completion of the Study or earlier termination of this Agreement as provided herein, the Institution shall reimburse the CRO for any amounts that were paid by the CRO to the Institution which exceed the amounts to which the Principal Investigator was entitled for completed Subject visits under the Budget and Payment Schedule of this Agreement.
- F. Payments for Screen Failure:** Sponsor will pay only **INR 1000 only per Subject for screen failure**. The maximum ratio for screen failure Subjects shall be **5:1** i.e. maximum one screen failure per **Five** randomized Subjects. Subject discontinued/withdrawn after screening will be considered as screen failure and payment for screen failure will be provided as per above mentioned statement.
- G. Payment for Study Coordinator:** PI will make sure payment to study coordinator / involved study team to ensure that the Quality and deliverables of the Project are not affected at any phase of the study.

#### **4. OBLIGATIONS OF THE INSTITUTION AND THE PRINCIPAL INVESTIGATOR**

- A. IEC/IRB Approval.** The Principal Investigator shall be responsible, with the cooperation of the Institution and Sponsor, for obtaining approval from the IEC / IRB of the Protocol and the Subject's Informed Consent Form. The Principal Investigator shall provide the Sponsor or Sponsor's designee with written confirmation of the IEC / IRB's approval prior to the treatment of Subjects. If the IEC/IRB withdraws approval of the Study, at any time, the Principal Investigator shall be immediately notify the Sponsor and/or CRO, providing a written explanation of the circumstances leading to such withdrawal of approval, and the Principal Investigator shall cease the treatment of all Subjects under the Study.
- B. Performance of the Study.** The Principal Investigator shall conduct the Study solely at the Institution. Principal Investigator will personally conduct or supervise the investigation of the Study. Principal Investigator will ensure that all persons assisting in the performance of the Study are informed of their obligations with regard to the Study. Principal Investigator agrees to report promptly, in writing, any non-compliance



of the Protocol. The Principal Investigator shall exercise due care in the conduct of the Study, and represent and warrant that it will be conducted in accordance with (i) generally accepted standards of good clinical and research practice (including, without limitation, the guidelines set forth by the International Conference on Harmonization, if applicable); (ii) this Agreement; (iii) the Protocol; (iv) written instructions provided by the Sponsor or Sponsor's designee; and (v) all applicable local, state and federal laws, regulations, and policies governing the performance of clinical investigations, including, but not limited to local regulatory requirements. In the event of a conflict between any requirements in (i) through (v) above, the Principal Investigator shall comply with the most stringent requirement. The Principal Investigator shall make no changes to the Protocol, except as agreed to and approved in writing by the Sponsor and, where required, the IEC/IRB. Neither the Institution nor the Principal Investigator shall subcontract any of its obligations or any portion of this Agreement to any other individual or entity without the prior written consent of the Sponsor.

**C. Key Personnel.** The Parties acknowledge that the participation of the Principal Investigator is essential to the successful performance and completion of the Study. If, for any reason, the Principal Investigator withdraws from the Study, becomes unavailable, or is otherwise unable to complete his responsibilities under this Agreement, the Principal Investigator shall immediately notify the Sponsor or Sponsor's designee and the Sponsor or Sponsor's designee shall endeavor to agree upon a successor. Absent prompt agreement upon a successor, the Sponsor may terminate this Agreement as set forth in Clause 12(B) below.

**D. Sponsor Visits.** The Sponsor's representatives may conduct periodic visits, at mutually acceptable times during normal business hours, to: (i) inspect and examine the Institution's facilities at which the Study is being conducted or was conducted; (ii) review the progress of the Study (including without limitation all source documents and data, and correspondence involving the IEC/IRB and applicable regulatory agencies); (iii) inspect and copy, at Sponsor's expense, any or all written and electronic data and work product relating to the Study; and (iv) collect financial billing and economic outcomes (including expense reports) provided that collection of such information is clearly described in the Informed Consent Form and appropriately authorized by the Subject and the IEC/IRB. The Principal Investigator and the Institution shall cooperate with the Sponsor and use reasonable efforts to promptly provide all of the information requested by the Sponsor.

The Institution and the Principal Investigator shall also cooperate with the Sponsor and with any regulatory agencies in the event of announced or unannounced monitoring, audit or inspection by such regulatory agencies. The Institution and the Principal Investigator shall notify the Sponsor by telephone of the intended or possible inspection within **twenty four (24) hours** of becoming aware of it; in addition, notice of the intended or possible inspection shall be sent to Sponsor within **forty eight (48) hours** of the telephonic notification. If a written response is required, the Institution and Principal Investigator shall permit representatives of the Sponsor to review and comment on such response prior to its being sent to the regulatory agencies. The Institution and Principal Investigator shall provide Sponsor with a copy of any report



received in connection with, or as a result of such inspection within **three (3) days** of its receipt.

**E. Supplies.**

- a. The Sponsor or Sponsor's designee shall supply to the Principal Investigator, at no charge, sufficient quantity of the Study Drug to conduct the Study, as well as the materials, equipment and information which the Protocol specifies. The Principal Investigator acknowledges that the Study Drug is experimental in nature, and therefore shall use prudence and reasonable care in the use, handling, storage, transportation, disposition and containment of the Study Drug and any of its derivatives. Within **thirty (30) days** following the completion or termination of the Study, all unused Study Drugs, devices and other materials that were furnished to the Institution by or on behalf of Sponsor shall, at Sponsor's expense, be returned to Sponsor, or if Sponsor so directs destroyed in accordance with instructions provided by the Sponsor. The Sponsor shall solely own all rights, title and interest in the Study Drug, including any materials derived therefrom and all intellectual property rights therein. The transfer of physical possession of the Study Drug hereunder, and/or the possession or use of the Study Drug by the Principal Investigator, shall neither constitute nor be construed as a sale, lease, or offer to sell or lease the Study Drug or other transfer of title in or to the Study Drug. Further, the Principal Investigator shall use the Study Drug solely for the conduct of the Study and in accordance with the Protocol unless they obtain the prior written authorization of the Sponsor.
- b. Any instruments, materials or other equipment supplied/provided by the CRO to the Principal Investigator shall be used solely for the purpose of conducting the Study and as per the Protocol/ Study requirements/ Study manuals under the Agreement. Also, any damage caused to the equipment supplied/provided by the CRO under the said Agreement or any repairing cost incurred in order to maintain the said equipment or repair the damage done while conducting the Study shall be borne solely by the Principal Investigator and no liability of the same shall be placed upon the CRO.

**F. Study Records, Reports, and Data.**

- i. Study Records. The Principal Investigator and the Institution shall, in a timely manner, prepare and maintain complete and accurate Study records as set forth in the Protocol and as may otherwise be required by applicable law, rule, regulation and good clinical practice ("**Study Records**"). The Principal Investigator shall make all Study Records, including, without limitation, source documents, signed Informed Consents, laboratory data, Drug inventory records, available to representatives of the Sponsor at the Sponsor's request. Except as otherwise expressly provided for in the Protocol or elsewhere herein, all Study Records shall be retained by the Principal Investigator for a period of **fifteen (15) years** after the approval of the Study Drug for marketing or the formal discontinuation of the clinical development of the Study Drug or as per instruction given by CRO/ sponsor for the same. Thereafter, prior to the disposal of the Study Records, Principal Investigator (as applicable) shall give



the Sponsor not less than **sixty (60) days** prior express written notice thereof, and if the Sponsor requests in writing, the Principal Investigator shall transfer the Study Records to the Sponsor at Sponsor's expense. Study Records shall in no event be destroyed without Sponsor's prior written permission.

All the source documents pertaining to clinical conduct of the study shall be treated as confidential. All the Study Records shall be the sole and exclusive property of the Sponsor excluding the source data.

- ii. Case Report Forms. The Principal Investigator shall complete full clinical evaluations and original CRFs on each Subject in accordance with the Protocol. The Principal Investigator shall ensure the accuracy, completeness, legibility and timeliness of the data reported to the Sponsor in the CRFs and in all required reports. In addition, the Principal Investigator shall deliver to the Sponsor or Sponsor's designee each completed CRF from monitoring visits as provided for in Clause 2(C) of this Agreement.
- iii. Annual Reports. The Principal Investigator shall submit written summaries of the status of the Study to the IEC / IRB annually, or more frequently, if requested by the IEC/IRB.
- iv. Final Reports. Upon completion of the Study, the Principal Investigator will provide a summary of the Study's outcome ("**Final Report**") to the IEC/IRB. In addition, any Serious Adverse Events will be reported to the IEC/IRB.
- v. In case the Principal Investigator is no longer associated with the Institute, Institute Head or authorized designee will be responsible for maintenance and retention of study records.

- G. Reporting of Serious Adverse Event. The Institution and Principal Investigator shall notify CRO/Sponsor of any Serious Adverse Event encountered in the Study within **twenty four (24) hours** of awareness of it in accordance with the instructions set forth in the Protocol. Each such notice shall be given by fax / mail, whether or not notification was initially given by telephone. The SAE reporting and follow up would be as per the current local applicable regulatory requirements.

## 5. CONFIDENTIALITY

- A. Confidential Information. The term "Confidential Information" shall mean any and all information, data or know-how, trade secrets whether written or oral, technical or non-technical, as well as tangible materials including without limitation (i) financial, accounting, and business information, (ii) information relating to samples, compounds, procedures, Protocol, the Study Drug and all reports, documents, data and other information generated in connection with the Study or other information which the Institution or the Principal Investigator receives, directly or indirectly, from Sponsor and/or CRO and (iii) any other data or information that is generated by the Institution as required by the Protocol and/or this Agreement, including Case Report Forms, laboratory data and Study results, but not including the medical records of the Institution. Subject to the provisions of Clause 5(A)(i) through 5(A)(iv), the Parties



shall not disclose Confidential Information without prior written authorization from the Disclosing Party for any purpose other than those specified in this Agreement. The obligations of non-disclosure shall not apply to the following:

- i. Confidential Information that is already in the public domain at time of disclosure or becomes publicly available through no fault of the Receiving Party;
- ii. Confidential Information that is already known to or independently developed by the Receiving Party as shown by its prior written records, provided that Receiving Party informs the Disclosing Party promptly upon the Receiving Party's discovery that the Confidential Information is already independently known to the Receiving Party;
- iii. Confidential Information that lawfully and in good faith received from a third party who did not derive it, directly or indirectly, from the Disclosing Party; and
- iv. Confidential Information required to be disclosed to a governmental or regulatory agency to the extent necessary for the required disclosure.

**Disclosing Party:** The term "Disclosing Party" shall mean the party disclosing Confidential Information to other party.

**Receiving Party:** The term "Receiving Party" shall mean the party receiving Confidential Information from the other Party.

**B.** Notwithstanding anything to the contrary in this Agreement, nothing herein shall (i) prevent the Institution from disclosing to the DCGI or any other appropriate regulatory agency Confidential Information (including Study results) that indicates that the administration or use of the Study Drug or device is associated with a serious risk of harm to the Subjects, provided that Institution furnishes at least fourteen (14) days advance written notice to the Sponsor and Sponsor fails during such time to either make the disclosure requested by Institution or to adequately demonstrate to the Institution that it has complied with all applicable disclosure requirements, or (ii) prevent Institution and/or Principal Investigator from informing the Subjects or potential Subjects of any adverse experiences or risks associated with the Study Drug or device.

**C. Non-Disclosure and Non-Use.** Except as otherwise expressly provided herein, for the term of this Agreement, and for a period of five (5) years thereafter, the Parties shall not disclose to any third party Confidential Information and shall not use for any purpose other than as expressly provided for herein any such Confidential Information, without the express written consent of the Disclosing Party. Without limiting the foregoing, the Parties shall disclose Confidential Information only to those employees of the respective Party who require such Confidential Information for the purposes of this Agreement and who are bound by an obligation of confidentiality and non-use no less stringent than set forth herein. Upon disclosing Confidential Information to any employee, the employing Party shall advise them of the confidential nature of the information, and shall require them to take all necessary and reasonable precautions to prevent the unauthorized disclosure thereof. In the event that the Parties are required to disclose Confidential Information pursuant to an order or requirement of a court,



administrative agency, or other governmental body, the Parties, as the case may be, may disclose the Confidential Information provided that the Receiving Party provides the Disclosing Party with reasonable advance notice thereof to enable the Disclosing Party to seek an appropriate protective order or to prevent the disclosure. In such a situation, the Receiving Party shall provide reasonable assistance to the other Party to obtain a protective order or to prevent disclosure.

**D. Medical Confidentiality.** Notwithstanding any of the foregoing, Sponsor shall maintain the confidentiality of all medical records, case history, test reports, fitness data and charts to which it may have access in accordance with all applicable federal, state and local confidentiality laws and regulations and its corresponding regulations issued under DCGI or other applicable regulations. Sponsor shall not use, disclose, maintain, store, or transmit any individually identifiable Subject information except as permitted by such laws

6. **Protection.** Without limiting the foregoing, the Parties shall maintain reasonable procedures to prevent accidental or other loss of any Confidential Information of the Disclosing Party, and shall use at least the same procedures and degree of care which each uses to protect its own confidential information, but in no case less than reasonable care. In the event of loss, disclosure or use of any Confidential Information in violation of this Agreement, the Receiving Party shall immediately notify the Disclosing Party. The Parties shall prevent the disclosure of medical records and private or personal information, whether confidential or not, to the extent required by applicable laws or regulations.

7. **PUBLICATION**

Subject to governing law, the Sponsor shall have the sole right to review, use, publish, and disclose any data, information, or results developed or arising out of the Study as the Sponsor, in its discretion, deems appropriate, including, without limitation, in submissions to the FDA and other governmental agencies. If Principal Investigator wants to publish his part, the prior written approval from Sponsor is required.

8. **OWNERSHIP OF MATERIALS, DATA, INVENTIONS, AND DISCOVERIES**

A. **Materials and Data.** The Sponsor shall solely own all right, title and interest in and to the Study Drug and any and all information, data or other materials delivered to the Institution or the Principal Investigator by or on behalf of the Sponsor as well as any derivatives, progeny, or improvements developed therefrom, and all intellectual property rights therein. Further, all data and work product arising out of or relating to the Study, including, without limitation, the Study Records, CRFs, reports, and specimens, and all intellectual property rights therein, shall be the sole property of the Sponsor. Accordingly, the Sponsor shall have, in its sole discretion, the right to publish, disclose, disseminate, and use, in whole or in part, the same for any and all purposes, including, without limitation, in and for submissions to the FDA or other regulatory agencies.

B. **Patents and Inventions.** All right, title and interest in and to, whether domestic or foreign any inventions or discoveries (collectively, "**Inventions**") first conceived of and reduced to practice prior to the Effective Date of this Agreement by the Principal Investigator, Institution or CRO as expressed in protocols, lab notebooks, or other



written records, the know-how incidental thereto, and any patent applications and resulting patents derived there from shall be the exclusive property of that Party.

- i. "New Invention or Discovery" shall mean any invention or discovery conceived and reduced to practice during and as a part of Study by the Principal Investigator or any faculty, staff, employees, students or agents of the Institution or the Principal Investigator, or jointly by such an individual or individuals with one or more employees or consultants of the Sponsor.
- ii. New Inventions or Discoveries made jointly by the Institution, Principal Investigator, or any of their respective agents with one or more employees or consultants of the Sponsor that: (a) are improvements to, new uses of, or (where applicable) new dosages or dosage forms of the Study Drug or device that arise from the performance of the research; or (b) occur during the performance of the Study and are based upon or subject to the claims of Sponsor's patentable Inventions shall be the sole property of Sponsor.
- iii. New Inventions or Discoveries arising out of the research performed under this Agreement solely by Institution, Principal Investigator, and/or any of their respective agents that is not covered by the provisions of Clause 7(B)(iii) (an "**Institution Invention**") shall be the sole property of Institution (subject to any agreement between the Institution and Principal Investigator regarding the ownership of inventions).
- iv. Institution and / or the Principal Investigator shall promptly notify the Sponsor a full written description of any New Inventions or Discoveries described in either Clause 7(B)(iii) or 7(B)(iv) of which they become aware. Sponsor shall have a time-limited, first option to negotiate an exclusive, worldwide, royalty-bearing license to any Institution Invention. Any such exclusive license shall include a reasonable royalty based on Sponsor's and Institution's respective contributions to Institution Invention and other terms that are typical in licenses of similar technology. Sponsor shall advise Institution in writing of its interest in obtaining an exclusive license to any Institution Invention within sixty (60) days of Sponsor's receipt of notice of Institution Invention. If Sponsor fails to notify the Institution within sixty (60) days or provides notice that it elects not to obtain an exclusive license, then Sponsor's option shall expire with respect to that particular Institution Invention and Institution shall be free to dispose of its interest in accordance with its technology transfer policies. If Sponsor and Institution fail to reach agreement on the terms for an exclusive license of a particular Institution Invention within four (4) months after Sponsor provides notice that it wishes to exercise its option, then for a period of one (1) year thereafter, the Institution shall not offer to license the Institution Invention to any third party on materially better terms than those last offered to the Sponsor without first offering such terms to Sponsor, in which case Sponsor shall have a period of thirty (30) days to accept the offer.

C. **No Other Rights.** Except as expressly set forth herein, none of the Sponsor, the Principal Investigator, or the Institution transfers to any other Party hereto, by



relate to Principal Investigator's activities under this Agreement, the Principal Investigator shall notify the Sponsor immediately and the Sponsor shall have the right to terminate this Agreement immediately without further cost or liability.

- B. Of the Sponsor.** The Sponsor represents and warrants that (i) it has the legal authority and right to enter into this Agreement, (ii) it has no obligation to any other party that is in conflict with the Sponsor's obligations under this Agreement, and (iii) this Agreement has been duly executed and delivered by it and constitutes a valid, binding obligation enforceable against it in accordance with its terms.

Sponsor represents and warrants to Institution and Principal Investigator the following: (i) any Study Drug or device administered or used in carrying out the Protocol has been approved by the DCGI or FDA or by the other regulatory agencies if applicable for investigational use; and (ii) Sponsor has at all times complied with and will continue to comply with all DCGI or FDA and comparable foreign rules, regulations, requirements, and guidelines regarding administration, manufacture, and production of drugs and devices under regulatory control of the DCGI or FDA and/or comparable foreign agencies in connection with any drug or device administered or used pursuant to the Protocol. In particular, Sponsor shall comply with all DCGI or FDA reporting rules that require it to inform Institution and/or Principal Investigator of any serious and unexpected adverse experience associated with the Study Drug or device.

- C. No Other Representations or Warranties.** Except for the limited representations and warranties given in this Clause 8, none of the Sponsor, the Institution, or the Principal Investigator makes or receives any representations or warranties, express or implied, statutory or otherwise, and each expressly disclaims any implied warranties of merchantability, fitness for a particular purpose, or non-infringement.

- D. Of the Institution:** Institution will ensure that the Principal Investigator remits to the Sponsor all clinical data, including without limitation, case record forms, medical reports and the information generated during the performance of the Study. Institution will notify the Sponsor immediately if the Principal Investigator ceases to be employed by or associated with the Institution.

## **10. GOVERNING LAW**

This Agreement shall be governed by and construed in accordance to the Laws of India. Disputes, if any, shall be arbitrated upon under the Arbitration and Conciliation Act, 1996 in English language and the venue shall be Ahmedabad, India. It is expressly agreed that the arbitral award shall be final and binding upon both the Parties hereto. However, the final jurisdiction shall lie with the courts of Ahmedabad, India. Each of the Parties hereby expressly submits to the jurisdiction of the courts of Ahmedabad, India.

## **11. INDEMNIFICATION**

- A. Sponsor Indemnification.** The Sponsor shall defend, indemnify, and hold harmless the Institution and its trustees, officers, the Principal Investigator, employees and agents (the "**Institution Indemnities**") from and against any liability, loss, damage, or expense (including reasonable attorneys' fees and expenses of litigation) incurred by or imposed upon the Institution Indemnities or any one of them in connection with any third party claims, suits, actions, demands, or judgments but only to the extent such



operation of this Agreement or otherwise, rights to any patent, copyright, trademark or other intellectual property right of any kind.

## 9. REPRESENTATIONS, WARRANTIES AND COVENANTS

**A. Of the Principal Investigator.** The Principal Investigator represents and warrants that (i) he has the legal authority and right to enter into this Agreement; (ii) he has no obligation to any third party that is in conflict with, or has the potential to conflict with, its obligations under this Agreement; (iii) he has and will maintain throughout the conduct of the Study, all training, information, licenses, approvals and certifications necessary for safely, adequately, and lawfully performing the Study; (iv) he will not enter into any agreement with any third party to directly or indirectly fund or support the Study without the express written consent of the Sponsor (excluding laboratory investigations, radiological investigations or any other requirement to fulfill Protocol criteria), and (v) this Agreement has been duly executed and delivered by it and constitutes a valid, binding obligation enforceable against it in accordance with its terms.

The Principal Investigator represents and warrants that no clinical study or trial in which he was involved was terminated for any reason prior to completion that was due, in whole or in part, to the Principal Investigator's non-compliance with the applicable protocol and/or safety requirements of the study or any applicable local, state or federal law. The Principal Investigator further represents and warrants that he has not received any written notice from the DCGI/FDA or NIH of any violation of any applicable federal law relating to clinical studies that has not been disclosed to the Sponsor and attached to this Agreement as an Exhibit hereto. For the purposes of the prior sentence, "written notice" shall include, but not be limited to, DCGI or FDA lists of Inspectional Observations (FDA Form 483), Notices of Adverse Findings, regulatory letters, warning letters, notices of intent to initiate clinical investigator disqualification proceedings under national regulations or under 21 C.F.R. 312.70 or 21 C.F.R. 812.119 or any similar regulation ("**Notice of Intent to Disqualify**"). The Principal Investigator further represents and warrants that he has never been disqualified from receiving investigational drugs or medical devices by the DCGI or FDA or NIH or any other federal governmental body. In the event that any of the foregoing events in this paragraph occur during the course of this Study, the Principal Investigator shall provide the Sponsor with a full written explanation of the circumstances of such an incident within ten (10) days of the occurrence of such an incident. If the Institution or the Principal Investigator becomes debarred as per the national or local regulations, this Agreement will immediately terminate. If the Principal Investigator receives a notice or threat of action with respect to its debarment or a Notice of Intent to Disqualify, the Sponsor shall have the right to terminate this Agreement immediately without further cost or liability. The Principal Investigator represents and warrants on his own behalf that he has not used, in any capacity, the services of any individual, corporation, partnership, or association which has been debarred, and neither shall use, in any capacity, the services of any individual, corporation, partnership, or association which has been debarred. In the event that the Principal Investigator becomes aware of the debarment or threatened debarment of any individual, corporation, partnership, or association providing services to the Principal Investigator which directly or indirectly



claims, suits, actions, demands or judgments arise from or are caused by the Study Drug and are not covered by insurance or self-insurance as set forth in Clause 11 and provided that the Study is conducted in accordance with (i) this Agreement and the Protocol; (ii) all written instructions provided by the Sponsor concerning the Study; (iii) all applicable federal, state, or local laws, rules, regulations, requirements, and policies; and (iv) the manner required of reasonable and prudent clinical investigators and physicians; and such loss does not arise out of the negligent or reckless conduct or omission or intentional misconduct or malfeasance of any Institution Indemnity, or any other person on the Institution's property or under its control, exclusive of the Sponsor's employees; and the Sponsor is notified within ten (10) working days of any complaint, claim, or injury relating to any loss for which indemnification and/or defense under this Agreement might be sought; and Principal Investigator and the Institution and its directors, officers, and employees fully cooperate with the Sponsor and its legal representatives in the investigation and defense of any claim or suit covered under this Agreement.

- B. Institution Indemnification.** The Institution shall defend, indemnify, and hold harmless the Sponsor and its affiliates and their respective directors, officers, employees, agents, successors, and assigns ("**Sponsor Indemnities**") from and against any and all third party liability, loss, damage, or expense (including reasonable attorneys' fees and expenses of litigation) incurred by or imposed upon the Sponsor Indemnities or any one of them in connection with any third party claims, suits, actions, demands, or judgments to the extent such claims, suits, actions, demands, or judgments arise out of: (i) a failure to conduct the Study in accordance with this Agreement and the Protocol, all written instructions provided by the Sponsor concerning the Study, all applicable federal, state, or local laws, rules, regulations, requirements, and policies, and in the manner required of reasonable and prudent clinical investigators and physicians; and (ii) the negligent or reckless conduct or omission or intentional misconduct or malfeasance of any Institutional Indemnity, or any other person on the Institution's property or under its control, exclusive of the Sponsor's employees.
- C. Notification.** The Parties shall promptly notify each other of any such claims, suits, actions, demands, or judgments and the Parties shall reasonably cooperate with each other in the handling thereof.
- D. Claims.** The indemnifying Party, at its own expense, shall have the exclusive right to manage claims, control investigation and litigation, and select counsel, including the right to compromise or settle any claims, actions, suits, demands, or judgments, provided that it shall not compromise or settle any such action with an admission of liability or wrongdoing by the indemnified Party without such Party's written consent.
- E. Representation.** In the event a claim or action is or may be asserted, the non-indemnifying Party shall have the right to select and obtain representation by separate legal counsel. If the non-indemnifying Party exercises such right, all costs and expenses incurred by the non-indemnifying Party for such separate counsel shall be fully borne by the non-indemnifying Party; provided, that without the Indemnifying Party's prior written consent, the non-indemnifying Party shall make no admission to,



or any settlement or agreement with, any person or party who is in any manner related to the liabilities for which indemnification may be sought by an non-indemnifying Party Indemnity.

- F. **Subject Injury.** Subject shall be entitled to financial compensation as well as reimbursement of reasonable and necessary medical expenses from the Sponsor in case of subject injury or death during clinical trial in accordance with Rule 122DAB of Drugs and Cosmetics Rules, 1945 as may be amended from time to time.

## 12. **INSURANCE**

- A. **Sponsor Insurance.** Sponsor shall maintain during the term of this Agreement and for a period of **One (1) year** thereafter, general liability insurance (with product liability endorsements) and professional clinical trial liability insurance coverage sufficient to meet its indemnification obligations in the appropriate amount Sponsor will provide evidence of its insurance upon request and will provide to the Institution, **thirty (30) days** prior written notice of cancellation of its coverage. Sponsor further agrees to include Institution and Principal Investigator as additional insured on such policy.

- B. **Institution Insurance.** Institution and Principal Investigator shall maintain during the term of this Agreement, general liability insurance and professional liability insurance coverage sufficient to meet its indemnification obligations on appropriate conditions and will provide to Sponsor and CRO thirty (30) days prior written notice of cancellation of its coverage.

This Clause 11 shall survive termination of this Agreement.

## 13. **TERM AND TERMINATION**

- A. **Term.** This Agreement shall begin on the Effective Date and shall remain in full force and effect until the completion of the Study and the submission of the Final Report pursuant to Clause 4(F)(iv), above, unless earlier terminated in accordance with this Agreement.

### **Termination**

- i. Either Party may terminate this Agreement immediately upon written notice to the other if:
  - a. the authorization and approval to perform the Study in India is withdrawn by the DCGI and/or other applicable regulatory authority in India;
  - b. animal, human and/or toxicological test results, in the opinion of either Sponsor or Institution, support termination of the Study; or
  - c. the circumstances require termination of Study in order to protect the safety, rights, or welfare of Subjects enrolled in the Study. In the alternative, either Party may immediately dis-enroll any Subject to protect that Subject's safety, rights or welfare without terminating this Agreement, but shall promptly give the other Party written notice of the dis-enrollment.
- ii. This Agreement may be terminated by either party, upon thirty (30) days prior written notice, if either of the following conditions occurs:



- a. if either Party fails to comply with the terms of this Agreement within thirty (30) days of receipt of written notice, with opportunity to cure, from the other Party; or
  - b. if the Principal Investigator is unwilling or unable (for whatever reason) to act as Principal Investigator and no mutually acceptable replacement has been found in accordance with Clause 4C of this Agreement.
- i. This Agreement may be terminated by either Party for any reason other than those listed in Clause 12(B) upon thirty (30) days prior written notice.
  - ii. Upon the effective date of termination, there shall be an accounting conducted by Institution, subject to verification by Sponsor. Within thirty (30) days after receipt of adequate documentation therefrom, Sponsor will make payment to Institution for.
    - a. all services properly rendered and monies properly expended by the Institution until the date of termination not yet paid for; and
    - b. Reasonable non-cancelable obligations properly incurred for the Study by Institution prior to the effective date of termination.
  - iii. Immediately upon receipt of a notice of termination, the Principal Investigator shall stop enrolling Subjects into the Study and shall cease conducting procedures on Subjects already enrolled in the Study as directed by Sponsor, to the extent medically permissible.
  - vi. **Immediate Termination by the Sponsor.** The Sponsor may terminate this Agreement, in whole or in part, effective immediately, upon written notice to the Principal Investigator; a) if the Sponsor, in its sole discretion, deems that the safety of the Subjects will be compromised by a delay in termination; or b) for any violation of the Study Schedule set forth in Clause 2) prior to the shipment of the Study Drug to the Institution.
  - vii. **Effect of Termination.** In the event this Agreement is terminated prior to completion of the Study, for any reason, the Principal Investigator shall a) notify the IRB that the Study has been terminated; b) cease enrolling Subjects in the Study; c) cease treating Subjects under the Protocol as directed by the Sponsor to the extent medically permissible and appropriate, and d) terminate, as soon as practicable, but in no event more than thirty (30) days after the effective date of termination, all other Study activities; provided, however, upon the Sponsor's request, the Institution and the Principal Investigator shall continue to collect data and prepare and complete CRFs for Subjects treated in the Study prior to termination. Within ninety (90) days from the effective date of any such termination, the Institution and the Principal Investigator shall provide to the Sponsor all data collected in connection with the Study, including, without limitation, Study reports and the Final Report described in Clause 4(F), above, and, except as otherwise provided herein, shall return to the Sponsor any and all materials and Confidential Information provided by the Sponsor for the conduct of the Study, at the Sponsor's expense, provided, however, that the Institution may retain one (1) copy of the Confidential



Information for record keeping purposes. The Sponsor shall remain liable for payment for any CRFs submitted prior to the effective date of termination, or within ninety (90) days thereafter, in compliance with the terms of this Agreement.

- viii. **Survival.** Termination of this Agreement by either Party shall not affect the rights and obligations of the Parties accrued prior to termination. All provisions in this Agreement which, by their nature, extend beyond termination of the Agreement, together with the provisions of Clauses 4(F), 5, 6, 7, 9, 10, 11, and 12 shall survive any termination of this Agreement for any reason.

#### 14. **MISCELLANEOUS**

- A. **Use of Names; Publicity.** Except as otherwise required by applicable law, regulation or court order, no Party to this Agreement will use the name or other identifying marks of any other Party or its affiliates or its employees in any advertisement, press release, or other public statement without prior written approval of the other Party; provided however that Sponsor may identify the Institution as a participating clinical site and the Principal Investigator as an investigator in a Study. The Institution and the Principal Investigator shall have the right to acknowledge the Sponsor's support of the research performed under this Agreement in scientific publications and other scientific communications (any such publications or communications shall be made in accordance with Article 6). Each of the Parties hereto shall not disclose to any third party the terms of this Agreement without the prior written consent of the other Party, except to advisors, investors, and others on a need-to-know basis under circumstances that reasonably ensure the confidentiality thereof, or to the extent required by law, regulation or court order.
- B. **Independent Contractors.** The Parties acknowledge that the relationship between the Sponsor, CRO, Institution and Principal Investigator created by this Agreement is that of independent contractors and that neither the Principal Investigator nor Institution or CRO may create or assume any obligation on behalf of the Sponsor.
- C. **Limitation of Liability.** In no event shall the Parties be liable to each other for any special, incidental, or consequential damages arising out of or relating to this Agreement, or the subject matter hereof, however caused and whether such claim is based in contract, tort (including negligence), or otherwise, even if an authorized representative of the Sponsor is advised of the possibility of such damages.
- D. **Notices.** Any notices required or permitted to be given hereunder shall be in writing, shall be addressed to the Party to whom such notice is intended as follows, or such other address and/or number as such Party may substitute by written notice hereunder, and shall be effective on receipt.

Any notice to the Sponsor shall be addressed as follows:

**Address:** **Morningside Healthcare Ltd**  
 Morningside House  
 Unit C, Harcourt Way  
 Meridian Business Park  
 Leicester, LE19 1WP  
 UK, Tel# +44116045950



Any notice to Institution shall be addressed as follows:

**Address : Father Muller Charitable Institutions**  
**Attn. : Rev .Fr. Richard Aloysius Coelho**  
**Director**

Any notice to Principal Investigator shall be addressed as follows:

**Address : Deapartment of Dermatology Venereology and Leprosy,**  
**Father Muller Medical College & Hospital,**  
**Father Muller Road , Kankanady ,**  
**Mangalore 575002, Karnataka, India**  
**Attn. : Dr. Ramesh Bhat M.**

Any notice to CRO shall be addressed as follows:

**Clantha Research Limited.**

Commerce House II, Opp. Pushparaj Towers, Nr. Judges Bungalows,  
Bodakdev, Ahmedabad - 380 054, Gujarat, India

**Attention : Dr. Dharmesh Domadia,**  
**Associate Vice President - Global Clinical Operations**  
**+91-79-66219 555 (phone)**  
**+91-79-66219 549 (fax)**

- E. Assignment.** This Agreement shall be binding upon and inure to the benefit of the Parties hereto, their respective successors, assigns, legal representatives and heirs. The Sponsor may assign this Agreement to any successor to all or substantially all of the business of the Sponsor, or in connection with its merger, consolidation, change in control or similar transaction. Except as otherwise set forth above, this Agreement may not otherwise be assigned by a Party (whether voluntarily, by operation of law or otherwise) without the prior written consent of the other Parties. Any purported assignment of this Agreement in violation of this section shall be void.
- F. Modification; Waiver.** This Agreement may not be altered, amended or modified in any way except in writing signed by the Sponsor, the Institution and the Principal Investigator. The failure of a Party to enforce any provision of the Agreement shall not be construed to be a waiver of the right of such Party to thereafter enforce the provision or any other provision or right.
- G. Entire Agreement.** This Agreement and its Exhibits constitute the entire agreement between the Parties with respect to the subject matter hereof and supersede all prior discussions, negotiations, communications, understandings, agreements, representations and writings with respect to all matters covered by the Agreement. In any conflict between the terms of this Agreement and the documents incorporated herein, the terms of this Agreement shall take precedence except as otherwise specifically set forth in this Agreement.
- H. Severability.** In the event that any provision of this Agreement is determined to be illegal, invalid or unenforceable by a court of competent jurisdiction, the remainder of this Agreement shall remain in full force and effect without said provision. The Parties shall negotiate in good faith a substitute clause for any provision declared illegal,



invalid or unenforceable, which shall most nearly approximate the original intent of the Parties in entering this Agreement.

- I. **Execution.** The Institution's IRB shall be the authorized representative of the Institution to approve the Protocol and any amendments thereto. This Agreement may be executed in one or more counterparts, all of which together shall constitute one and the same agreement. This Agreement may be executed by facsimile signature.
- J. **Changes to the Protocol.** If at a future date changes in the Protocol appear desirable, such changes may be made through prior written agreement between Sponsor and Institution. If such changes affect the cost of the Study, Institution will submit to Sponsor a written estimate for approval. If in the course of performing this Agreement, however, generally accepted standards of clinical research and medical practice relating to the safety of Subjects require a deviation from the Protocol, such standards will be followed. In such case, the Party aware of the need for a deviation will immediately inform the other of the facts causing such deviation as soon as the facts are known to the Party.
- K. **Covenant Not to Hire.** Sponsor shall not, and shall not permit any of its affiliates to, employ or offer to employ any Key Personnel (as defined in this Section) until one year following termination or expiration of this Agreement, unless Institution, or Institution's affiliate, as the case may be, gives its written consent thereto. "Key Personnel" shall mean those individuals employed by Institution, who perform research related services for Institution or any of its affiliates, including, but not limited to, persons serving as research coordinators and grant account managers.
- L. **Drug Safety and Reporting.** The recording of adverse events (AEs) is an important aspect of the Study documentation. It is the Principal Investigator's responsibility to document all AEs according to the detailed guidelines of the Protocol. The Principal Investigator agrees to answer any questions of SPONSOR and/or CRO's Medical Monitor concerning any AEs and also any follow-up queries from the regulatory authorities to the Sponsor. According to the Protocol, the Principal Investigator will assess at each visit whether any adverse event (AE) including abnormal laboratory values has occurred. The details of all AEs, whether reported by the Subject or observed by the Principal Investigator / Study personnel during the entire Study, will be recorded onto the appropriate source document. Each adverse event must be recorded in the AE section of the case report form (CRF), regardless of the causal relationship.

The Principal Investigator must immediately report all serious adverse events (as defined in Protocol), which occur during the course of the Study and up to the date of the Subject's last visit, to the addressee given below. The SAE Report form will be used for documentation and reporting.

Initial and follow up SAE reports are to be faxed / Mail the Medical Affairs Department of CRO for onward transmission to SPONSOR:



Name: Dr. Ankesh Barnwal  
SAE Fax number: +91-79-6621-9541  
Telephone numbers: +91-79-66219500  
Cell number: +91-9909019497  
E-mail: [abarnwal@cliantha.in](mailto:abarnwal@cliantha.in)

If the event is unexpected and fatal or life threatening and is considered by the Principal Investigator possibly related to the Study medication, the Drug Safety Department of CRO shall be informed immediately by telephone and followed immediately by fax/ Mail.

CRO undertakes to notify the Principal Investigator and SPONSOR of all serious unexpected adverse events, which occur during the course of the Study in any other location and are reported in an expedited manner to health authorities. The Principal Investigator will inform the local ethics committee of SAEs reportable according to its national requirements and timelines, and of findings that could adversely affect the Subject's safety, could have an impact on the conduct of the Study, or could alter the ECs / IRB's approval to continue the Study.

CRO will be responsible to notify on time the health authorities in India.

IN WITNESS WHEREOF, the undersigned have entered into this Agreement as of the date first set forth above.



**INSTITUTE**

By: \_\_\_\_\_

(Signature & Date)

REV. FR RICHARD ALOYSIUS COELHO  
Director  
Father Muller Charitable Institutions  
Fr Muller Road, Kankanady  
MANGALORE-575002

Rev .Fr. Richard Aloysius Coelho  
Director

BY EXECUTING THIS DOCUMENT IN THE SPACE PROVIDED BELOW, THE  
PRINCIPAL INVESTIGATOR HEREBY ACKNOWLEDGES AND AGREES TO COMPLY  
WITH THE TERMS OF THIS AGREEMENT AND THE APPLICABLE PROTOCOL, AS  
AMENDED FROM TIME TO TIME

**PRINCIPAL INVESTIGATOR**

By: \_\_\_\_\_

(Signature & Date)

Dr. Ramesh Bhat M.  
Principal Investigator

DEPT. OF DERMATOLOGY,  
VENEREOLOGY AND LEPROSY  
Fr. Muller's Medical College  
Kankanady, Mangalore-575 002.

**CLIANTHA RESEARCH LIMITED**

By: \_\_\_\_\_

(Signature & Date)

Dr. Dharmesh Domadia,  
Associate Vice President - Global Clinical Operations





**EXHIBIT B: BUDGET AND PAYMENT SCHEDULE****Principal Investigator: Dr. Ramesh Bhat M.**

**Site Address** : Deapartment of Dermatology Venereology and Leprosy,  
 Father Muller Medical College & Hospital, Father Muller Road , Kankanady  
 , Mangalore 575002, Karnataka, India

**BUDGET:**

<b>CRL111735: Per Patient Grant</b>					
<b>Investigator Grant (All amounts in INR)</b>					
<b>Patient Visits</b>	<b>PI Charges</b>	<b>Lesion Photographs</b>	<b>Study Coordinator</b>	<b>Patient travel compensation</b>	<b>Total Grant Visit vise per Patient</b>
Screening, Visit-1	2500	×	2000	500	5000
Baseline, Visit-2	1500	750	1000	500	3750
Week-2, Visit 3	1000	×	500	500	2000
Week 5, Visit 4	1000	×	500	500	2000
Week 8, Visit 5	1000	×	500	500	2000
Week 11, Visit 6	2000	750	500	500	3750
Safety FU, Visit 7(EOS)- Telephonically	1000	×	500	×	1500
<b>Total Grant</b>	<b>10000</b>	<b>1500</b>	<b>5500</b>	<b>3000</b>	<b>20,000</b>

<b>Total Per Patient (INR)</b>	<b>20,000</b>
Institutional Overhead (20%)	<b>4,000</b>
<b>Grand Total</b>	<b>24,000</b>

***Budget notes, payment schedule, conditions of payment and payment directions***

*Note 1: Patient travel reimbursement with maximum cap of INR 500 per visit based on actual patient travel invoices/bill.*

*Note 2: AE/SAE compensation and/or medical management as per Regulatory Requirement (During SAE management consultant charges if any, will be provided only for consultant who is not a part of study team. Consultant who is part of study team will not be reimbursed for extra visit/charges)*

*Note 3: Screenfailure payment will be done on 5:1 basis i.e. maximum one screen failure per Five randomized patient*

**Grand total is Exclusive Archival charges or any other charges**

**Study Start-Up cost (Advance Payment) of INR 25,000/- will be provided to the PI which will be adjusted against first two invoices raised by PI as per the PI grant.**

**PAYMENT SCHEDULE**

Payment Schedule for the total study Grant for patients is as follows:

**Overall Per Patient Budget****Overall Per Patient Budget: INR 24,000.00/- inclusive of all applicable charges**

The Payee designated above will receive all compensation paid to the Institution in connection with the Investigator Agreement, if applicable. Payee will provide all applicable tax identification numbers and, upon reasonable request, will provide or assist CRO with forms related to applicable taxes.

**Payment Schedule for the other payments is as follows:****Study start-up cost (Advance payment) INR. 25000/- (Twenty five thousand only)**

The advance payment provided to the PI will be adjusted against first two invoices raised by PI as per the PI grant.

Sponsor will pay only **INR. 1000/-** amount for screen failure patients as per Exhibit A of this agreement with the maximum ratio of 5:1 i.e. maximum one screen failure per Five randomized patients. Any Study subject who has been enrolled in the Study but does not meet eligibility requirements (as set forth in the Protocol) may be withdrawn from study without any payments. CRO reserves the right to withhold payment for any Study subject: (i) for whom a signed informed consent form has not been obtained prior to enrollment, (ii) for whom reasonably complete Case Report Forms have not been obtained, or (iii) for whom the Protocol has not been followed, absent reasonable explanation from Institution and/or Principal Investigator for the Protocol deviation(s).

**Payment Adjustments**

If Institution's/ Principal Investigator's participation is terminated because no Study subjects have been enrolled, Institution/Principal Investigator will not be entitled to reimbursement or payment for any administrative costs that were incurred prior to such termination, except to the extent such costs are set forth expressly in this Investigator Agreement.

If, upon termination of this Investigator Agreement, CRO, on behalf of Sponsor, has prepaid funds that Institution/Principal Investigator has not earned in accordance with Exhibit A, Institution/Principal Investigator (or its designated payee) will return to CRO all such prepaid funds within **thirty (30) days** after the effective date of termination. Prepaid funds owed to CRO, if any, will be returned pursuant to instructions provided by the CRO accountant assigned to administer payments to the Payee.

In the event this Exhibit A sets forth a maximum number of subjects that may be enrolled by Institution in the Study or a maximum payment amount to Payee pursuant to the Study, Sponsor at its discretion may authorize increases in Study subjects and/or payments.

In the event the Protocol is amended, compensation paid to the Payee may be adjusted to give effect to the Protocol amendment.

During the course of the Study, Institution will have **forty five (45) days** after the receipt of final payment to dispute any reasonable payment discrepancies.

**Confidential**

CRL111735 Study

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**Invoices:**

Send invoices to : Cliantha Research Ltd.  
 Contact Person: Devesh Verma  
 Address : Cliantha Research Ltd., Garden View Corporate House No. 08,  
 Opposite AUDA Garden, Bodakdev, Ahmedabad - 380054, Gujarat

Failure to include Protocol number and Principal Investigator's name on all invoices may result in delayed payment.

**Final Payment**

The final payment will be made after the close-out visit by the CRO CRA, after all CRFs for all subjects have been received and accepted by a CRO project leader, and all data queries for Institution have been resolved satisfactorily.

**Budget notes, payment schedule, conditions of payment and payment directions**

1. All amounts above are in Indian Rupee (INR).
2. The lab investigations at screening and end of study would be performed at central lab (Clantha Research Ltd., Ahmedabad). The study site payment (Investigator grant, CRC grant, CT Scan charges, Miscellaneous charges etc.) would be made visit wise (upon completion of visits at site by the patient).
3. Serious Adverse event related costs: Costs relating to SAE that arise due to study participation would be borne by the Sponsor on actual.
4. Please note that approx. 20 % of the amount for one randomized patient only will be considered as retention amount and will be paid at the end of study/ study close out; once all the study related procedure and documentation would be over.
5. All payments are subject to withholding tax under all applicable laws including GST
6. GST will be deducted and applicable as per current government rules and regulations (i.e. on date of invoice).
7. GST (as applicable) will be considered on total grant subject to availability of service tax registration number with service provider. Service tax will be paid and applicable to service provider, provided to reflect the service tax registration number on Invoice / Bills."
8. In case recruitment is not initiated within a reasonable time period, unutilized amount (In keeping with the payment head above) would have to be returned to Sponsor.

# Memorandum of Understanding

By And Between

**FATHER MULLER CHARITABLE INSTITUTIONS, MANGALURU**

And

**INDIAN CANCER SOCIETY, BENGALURU**

This **MOU** is entered into on the 17<sup>th</sup> Day of December, 18 (hereafter the "Effective Date") by and between:

**Indian Cancer Society, Bengaluru**, with its registered office at CA Site 1, Mahabodhi Meditation Centre, Siddapur Road, Jayanagar 1st Block, Bengaluru, Karnataka 560011 (hereafter "**ICS**");

And

**Father Muller Charitable Institutions** at Kankanady, Mangalore 575002 (hereafter **FMCI**)

who are referred to, collectively, as "Parties" or, individually, as "Party".

## PREAMBLE:

**WHEREAS** FMCI and ICS, recognize the benefits to be derived from collaboration, cooperation and mutual interaction for the development and promotion of joint activities to address issues of mutual interest, designed to foster and promote collaboration in the field of cancer education, screening and detection.

## **NOW THE PARTIES HAVE AGREED AS HEREUNDER:**

### **1) NATURE AND SCOPE OF JOINT ACTIVITIES:**

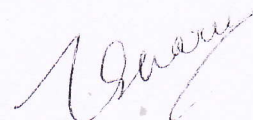
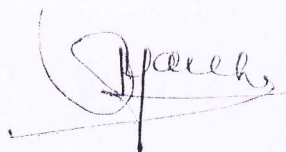
The parties have agreed to undertake the following activities jointly:

- a) Cancer education and awareness in general public
- b) Screening & Detection of Oral, Breast and Cervical Cancer in rural setting.
- c) Follow up on Cancer screened individuals.

Activities and responsibilities for undertaken under this MoU are listed in Annexure 1 and 2.

### **2) INTELLECTUAL PROPERTY:**

- a) All material and information provided by either Party under this MOU towards the activities envisaged shall remain the exclusive property of such Party and the Other Party does not and shall not derive or be deemed to have acquired any right, title or interest in the same.





- b) Each Party to this MOU represents that it shall not infringe or cause to be infringed any intellectual property rights of the other Party including any brand name, logo, trade name or those associated with any information or material provided under this MOU and shall keep the same strictly confidential.

**3) PUBLICITY & MARKETING:**

Both Parties agree to consult each other in case of any requirement for publicity of the said project to the media or any other agency and to act diligently in the best interest of the project.

**4) CONFIDENTIALITY:**

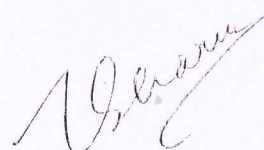

- a) Both Parties shall treat as strictly confidential and prevent disclosure thereof, of all Confidential Information exchanged pertaining to the Activities under this MOU including, but not limited to, information related to any processes, techniques, plans, formulations, products, testing, storage and other methodologies and norms, services, trade secrets and other technical knowledge and the fact and contents of and relating to this MOU between FMCI and ICS ("Confidential Information"). Both parties shall not disclose or use such Confidential Information for any other Party in any manner and shall only use such information for the purposes of this MOU.
- b) Confidential Information does not include information which
- (i) at the time of such disclosure was, or subsequently became, publicly available (other than as a result of its disclosure by either Party, in breach of this MOU);
  - (ii) at the time of such disclosure, was or subsequently became available on a non-confidential basis from a third Party source provided that such source was not subject to any duty of confidentiality in respect thereof; or
  - (iii) has been independently acquired or developed by it without relying on any information or material which is disclosed by or available from the other Party or by breaching any of its obligations under this MOU.

**5) TERMS OF MOU:**

This MOU shall come into force from the **Effective Date** and shall remain in force for a period of 5 years (60 months), from the Effective Date of the MOU. The Term of the MOU may be mutually extended on terms mutually agreed to by the Parties.

**6) TERMINATION:**

- a) On non-performance of the obligations as specified in this MOU, either Party shall be entitled to terminate this MOU for any such breach of the terms of the MOU remains uncured for a period of 15 working days from the date of





the notice to cure such breach. For the purpose of this clause, any breach of the terms of the MOU shall be deemed to have taken place from the date of the receipt of written intimation that a claim of breach has been raised.

- b) Notwithstanding anything contrary stated hereinabove, both parties shall have the right to terminate this MOU without assigning any reasons by giving 30 days written notice to the Other Party.

**7) FORCE MAJEURE:**

- a) Neither Party shall be liable for any failure or delay in performance under this MOU to the extent the said failures or delays are proximately caused by causes beyond that Party's reasonable control and occurring without its fault or negligence, including, without limitation, performance failures of parties outside the control of the contracting Party, Acts of God, War, Floods, Earthquakes, Strike, Lockouts, Epidemics, Riots, Civil Disturbance among others, provided that, force majeure will apply only if the failure to perform could not be avoided by the exercise of due care by the Party invoking this clause and such Party does everything reasonably possible to resume its performance under this MOU.
- b) A Party affected by an event of force majeure shall give the other Party written notice, with full details as soon as possible and in any event not later than fourteen calendar days of the occurrence of the cause relied upon. If force majeure applies, dates by which performance obligations are scheduled to be met will be extended for a period of time equal to the time lost due to any delay so caused. However, if the performance of the MOU is delayed beyond eight (8) weeks from the date of this MOU either Party may, at its discretion, terminate this MOU.

**8) GENERAL:**

a) Severability:

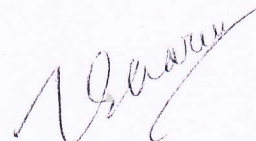
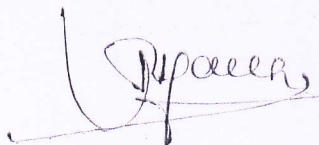
If any provision of this MOU is found by any court of competent jurisdiction to be invalid or unenforceable, the invalidity of such provision shall not affect the other provisions of this MOU; and all provisions not affected by such invalidity shall remain in full force and effect.

b) Waiver:

The waiver by either Party of a breach or default in any of the provisions of this MOU by the other Party shall not be construed as a waiver of any succeeding breach of the same or other provisions; nor shall any delay or omission on the part of either Party to exercise or avail itself of any right, power or privilege, operate as a waiver of any breach or default by the other Party.

c) Relationship:

This MOU is being entered into on a principal-to principal basis.





d) Notices:

Any notice shall be given by way of registered post with Acknowledgment Due at the address given in the description of the Parties. Email communications shall not be accepted as valid legal notices. The address and other details of the Parties for the purpose of communication, unless otherwise notified in writing, to the other Parties shall be as provided in this MOU.

e) Binding Nature and Assignment

- i. This MOU shall be binding upon and inure solely to the benefit of the parties hereto and their successors and permitted assigns and nothing in this MOU shall confer upon any other person or entity any legal or equitable right, benefit or remedy of any nature whatsoever under or by reason of this MOU. Neither Party shall have the power to assign or transfer this MOU without the prior, written consent of the other Party.
- ii. This MOU constitutes the entire MOU between the parties hereto. There are no prior or contemporaneous, oral or written, representations, understandings or MOUs, which are not fully expressed in this MOU.

f) Amendment

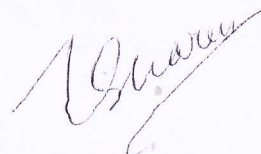
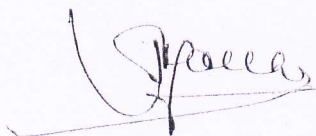
No amendment, change order, waiver or discharge shall be valid unless it is in writing and signed by an authorized representative of the Party against whom such amendment, change order, waiver or discharge is sought to be enforced.

g) Limitation of Liability:

In no event shall either party be liable to the other party or any other entity for any kind of losses including analyst profits, or for any indirect, special, consequential or incidental damages arising out of this MOU, under any cause of action, whether or not such party or its agents have been advised of the possibility of such damage.

h) Dispute Resolution

- i. Any dispute or difference arising between the parties under this MOU or the implementation of the obligation arising there from shall be discussed mutually and resolved within a period of 30 days.
- ii. In the event that no such mutual settlement is reached, any and all disputes arising out of or in relation to this MOU shall be subject to the exclusive jurisdiction of the courts at Bengaluru, Karnataka, to the exclusion of all other courts.



i) Designated contact persons for parties to the MOU

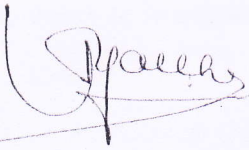
All notices, communication under this MOU will be sent by Registered AD and shall be addressed to:

For FMCI: Rev. Fr Richard Aloysius Coelho  
Administrator  
Father Muller Charitable Institution,  
Kankanady, Mangaluru 575 002

For ICS: Mr. Vijay Sharma,  
Honorary Secretary  
Indian Cancer Society

IN WITNESS WHEREOF, the parties to this MOU, intending to be legally bound, have duly executed this MOU to become effective as of the date first written above.

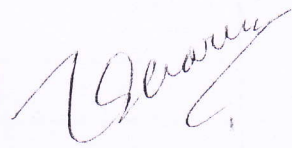
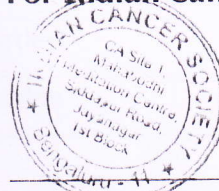
**For Father Muller Charitable Institution**



**Rev. Fr Richard Aloysius Coelho**  
Administrator  
Father Muller Charitable Institution

**REV. FR RICHARD ALOYSIUS COELHO**  
Director  
Father Muller Charitable Institutions  
Fr Muller Road, Kankanady  
MANGALORE-575002

**For Indian Cancer Society**



**Mr. Vijay Sharma**  
Honorary Secretary  
Indian Cancer Society



## ANNEXURE 1

**Name of Project:** Cancer screening & Awareness Camps in and around Mangalore.

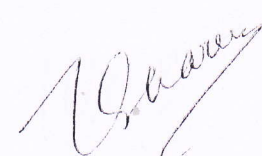
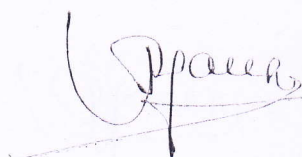
**Project Objective:**

1. Early diagnosis of certain types of cancer & follow-up with probable cases to initiate medical treatment.
2. To reduce the incidence of Cancer disease through awareness sessions.

**Project Activities and Responsibilities:**

Activity	Responsibility
Organize Camps	Both Parties
Assign Medical & Nursing Staff to screen for Cancer	FMCI
Assign Volunteers to manage the camp	Both Parties
Pre Camp Survey	Both Parties
Define Process for Cancer Detection Camps in Mangalore region	ICS
Transport Arrangement	FMCI
Maintain Registration Details and track probable cases	Both Parties
Maintain, report and track the referred probable cases	Both Parties
Counselling Cancer Probable Cases	Both Parties
Follow-up diagnostic and treatment	ICS & FMCI
Pathology and investigation charges	ICS, subject to terms & conditions and limits mentioned further below
Camp materials – Consumables ( PAP smear kit, slides, Spatula, fixative agents, staining materials)	ICS

Other than the above, both Parties agree that they will bear their respective costs with respect to the above activities.



Reimbursement will be done by ICS to FMCI at the following rates:

A. Investigations:

Sl No	Investigation	Cost in Rupees
1.	PAP Smear	No reimbursement will be made, as under the agreement the PAP smear Kit will be provided by ICS and the procedure will be carried out by personnel from FMCI.
	Mamogram	
	Single breast	600
	Both breasts	900
3.	Biopsy	210
4.	FNAC	330
5.	Cytology	120

**ANNEXURE 2**

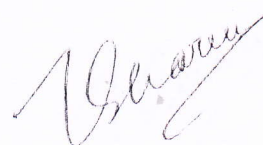
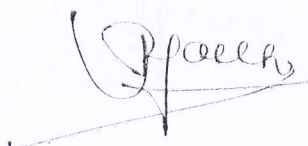
Treatment for individuals screened in ICS camps and diagnosed with cancer:

- FMCI will utilize the insurance schemes under which the patient is covered for expenses incurred during treatment.
- If the patient is not covered by any insurance scheme and is unable to meet the costs of treatment, by any other means, FMCI will send the Application for treatment, along with required supporting document to ICS.
- ICS would review each application and, provide financial support up to 2 patients in a quarter, to a maximum of Rs 25,000 per patient, to meet the initial cost of treatment, subject to the satisfaction of certain criteria and the discretion of the ICS management.

It is understood by both Parties that it is not mandatory for ICS to provide such financial support.

Qualifying Criteria for Funding of Initial Treatment:

- Only those patients whose current family income does not exceed Rs.2,00,000 per annum would be considered eligible for aid.
- The patient must undergo treatment only at the empanelled hospital from which the application is received.
- The patient must be registered as a general ward patient (not private or semi-private).

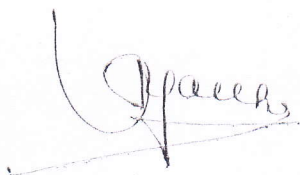
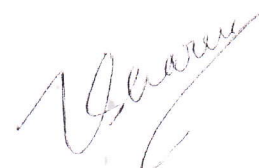




- To be eligible for initial treatment funding, young patients (below age of 18 years) need to have a projected five-year survival of 70% or more.
- To be eligible for initial treatment funding, adult patients (18 years or above) need to have a projected five-year survival of 50% or more.

The funds would be disbursed for initial treatment only.

ICS would have the right to audit the records of FMCI to the extent necessary, to ensure proper utilization of the funds disbursed by ICS

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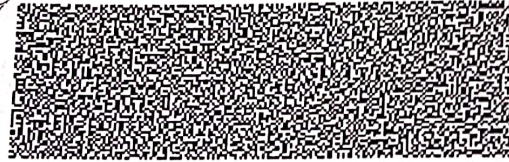
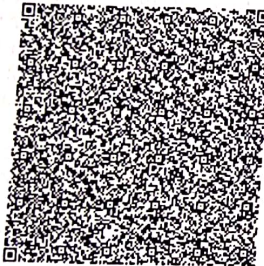
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INDIA NON JUDICIAL

## Government of Karnataka

e-Stamp

Certificate No.	: IN-KA18803613955563R
Certificate Issued Date	: 01-Jan-2019 11:20 AM
Account Reference	: NONACC (FI)/ kaks/cl08/ KANKANADY/ KA-DK
Unique Doc. Reference	: SUBIN-KAKAKSFCL0872571906254021R
Purchased by	: FATHER MULLER MEDICAL COLLEGE HOSPITAL MANGALORE
Description of Document	: Article 12 Bond
Description	: MOU
Consideration Price (Rs.)	: 0 (Zero)
First Party	: FATHER MULLER MEDICAL COLLEGE HOSPITAL MANGALORE
Second Party	: SPARSHA DIAGNOSTICS
Stamp Duty Paid By	: FATHER MULLER MEDICAL COLLEGE HOSPITAL MANGALORE
Stamp Duty Amount(Rs.)	: 100 (One Hundred only)



Please write or type below this line

## MEMORANDUM OF UNDERSTANDING

This Memorandum of Understanding (herein after referred to as "MOU") is made and executed on this date **January 7, 2019** at Mangalore

  
Rudolph Ravi D'Sa  
ADMINISTRATOR  
Father Medical College Hospital  
Mangaluru-575 002



**Dr. MURALI KESHA S.**  
MEDICAL DIRECTOR  
**SPARSHA DIAGNOSTICS**  
Ground Floor, "Vishwas Springfield"  
Opp. Hotel Maya International  
Upper Bendoor, Mangalore - 575 002

### Statutory Alert:

1. The authenticity of this Stamp Certificate should be verified at "www.shcilestamp.com". Any discrepancy in the details on this Certificate and as available on the website renders it invalid.
2. The onus of checking the legitimacy is on the users of the certificate.
3. In case of any discrepancy please inform the Competent Authority



**BY AND BETWEEN**

Father Muller Medical College Hospital, Mangalore (a unit of Father Muller Charitable Institutions) situated at Father Muller Road, Kankanady, Mangaluru - 575002 represented by Rev. Fr Rudolph Ravi D'Sa, Administrator (hereinafter referred to as "FMMCH") which term unless repugnant to the context thereof, shall mean and include its successors-in-interest and permitted assigns, of the FIRST PART

AND

Sparsha Diagnostics, its office at Ground Floor, Vishwas Springfield, Opposite Maya International Hotel, Upper Bendoor, Mangaluru, duly represented by Medical director (hereinafter referred to as "Sparsha") which term unless repugnant to the context shall mean and include its successors and permitted assigns) of the SECOND PART

"FMMCH" and "Sparsha" are individually and collectively referred to as "Party" and "Parties" respectively.

**WHEREAS**

1. Father Muller Medical College Hospital Laboratory, a division of Father Muller Medical College Hospital is a clinical laboratory delivering specialized testing facilities in the field of Biochemistry, Hematology, Histopathology and Microbiology.
2. FMMCH offers Inter Laboratory Quality Control specialized pathological diagnostic services on a per-request basis from similar health care facilities.
3. Sparsha owns and operates a hospital, requires services of the type offered by FMMCH.
4. Sparsha desires to obtain services from FMMCH and FMMCH is willing to provide such services to Sparsha, in accordance with the terms and conditions set forth within.

Wherefore, it is agreed between the Parties as under:

**1. Term**

- 1.1 This agreement shall be a valid for a period of one year from the date of execution of this agreement. This agreement shall come into effect from January 7, 2019. However either party will renew this agreement for further period of one year with mutual consent.

**2. Objective**

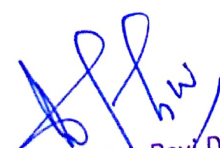
- 2.1 The objective of this MOU is to establish a written document framing a basic understanding under which both the parties shall be governed for conducting diagnostics and monitoring tests on the samples received by Sparsha.

**3. Scope of Work**

- 3.1 During the term hereof or the extended term as the case may be FMMCH shall provide the services to Sparsha for all the tests requested by Sparsh. The list of tests annexed to this agreement as **Annexure 1**.

**4. Role and Responsibilities of Father Muller Medical College Hospital**

- 4.1 FMMCH shall conduct tests/investigations as per duly filled request form filled by Sparsha. The testing and reporting shall be carried out conforming to prevalent high standards of quality.

  
Fr Rudolph Ravi D'Sa  
ADMINISTRATOR  
Muller Medical College Hospital  
Mangaluru - 575 002

  
Dr. MURALI KESHAVA S.  
MEDICAL DIRECTOR  
SPARSHA DIAGNOSTICS  
Ground Floor, "Vishwas Springfield"  
Opp. Hotel Maya International  
Mangalore - 575 002

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4.2 FMMCH shall provide reports of tests/ investigations through hard copy by courier.

4.3 FMMCH shall conduct tests/investigations on the basis of samples received from Sparsha. The sample received from Sparsha shall be tested and reported within two or three working days under normal circumstances. Reporting timeliness will be in accordance with prevalent quality standards.

#### 5. Roles and Responsibilities of Sparsha

5.1 Sparsha shall be responsible for proper packing of samples and transportation in defined condition and temperature. Hospital will not be responsible for packing and transportation.

5.2 Sparsha shall be responsible for sending duly filled test requisition form, patient history, samples packing and labeling at required temperature in good condition to FMMCH for test/ investigations.

5.3 Sparsha shall make payments to FMMCH for services provided under this MOU within 15 days of receiving the invoices.

5.4 It is the responsibility of Sparsha to provide additional details requested by FMMCH to conduct the test/ investigation.

#### 6. Force Majeure

6.1 Any delay in reporting the test/ investigation shall be subject to Force Majeure, such as unavailability of test kits, failure of test, incomplete patient / test details, problem sample, need for repeat sample/ testing, instrument or machinery breakdown, civil unrest, riots, change in or in the interpretation of laws, strikes, lockout or other labour problems, unavailability of supply, fire or explosion, act of terrorism and other natural calamities. FMMCH would make efforts to mitigate the impact of such Force Majeure conditions and ensure timely testing as feasible and inform Sparsha accordingly.

#### 7. Consideration:

7.1 The billing shall be done on monthly basis starting from 1<sup>st</sup> to 31<sup>st</sup> of each month and Sparsha undertakes to clear all the outstanding payments within 15 days from the date of receiving the invoices.

7.2 Revision of tariff by FMMCH will be intimated to Sparsha in writing, upon which the revised rate tariff shall be applicable from the date revision.

#### 8. Termination and Consequences of Termination

8.1 Each of the parties makes the following representations and warranties to the other party hereto that the representing party has the full power and unrestricted authority to enter into this MOU. Entering this MOU and performing the obligations hereunder does not conflict with and is not prohibited under the terms of any other agreement, document, law, rule, regulation or court order to which the representing party is subject. Each of the parties has the full power and unrestricted authority to grant the licenses that are granted herein.

#### 9. Termination and Consequences of Termination

9.1 This MOU may be terminated on mutual consent or by either party with at least 30 days prior written notice without assigning any reasons.

9.2 All payments due, becoming due and payable to the Parties as on the date of termination, under the terms of this MOU shall continue to be due and payable to the Parties notwithstanding the termination hereof.

#### 10. Confidentiality:

10.1 Each Party shall keep secret all Confidential Information, if any, transmitted to it or made available to it by the other Party and shall not pass such Confidential Information on, wholly or partly, to third parties without express written consent of the other Party.

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Dr. Ravi D'Sa

*[Signature]*

**Dr. MURALI KESAVA S.**  
MEDICAL DIRECTOR  
SPARSHA DIAGNOSTICS  
"Vishwas Springfield"



10.2 The Parties shall not disclose the terms of this MOU or make any announcement in respect of the subject matter thereof without prior written consent of the other Party unless the disclosure is required by law or other regulatory authorities. In the event disclosure is required by law, rules or regulations, such disclosure shall be made after obtaining written permission of other party.

10.3 The Confidentiality obligations in this do not apply to disclose information that either Party in writing can prove that:

- i. It was known at the time of disclosure to be free of any obligation to keep it confidential, as evidenced by written records.
- ii. Became generally publicly known through authorized disclosure.
- iii. The information was independently developed without access to or use of any confidential Information, as evidenced by written records, or
- iv. The information was rightfully obtained from a third party who had the right to transfer or disclose it without violation of any confidentially obligations.

### 11. Dispute Resolution and Governing Law

11.1 In case if any difference or dispute arises between the Parties herein, the Parties shall hold mutual discussions to resolve such difference and / or dispute in an amicable manner for the best interests of both Parties. Parties shall try to resolve the difference and / or dispute within 30 days or such extended time as agreed between the Parties. In case, any difference and / or dispute could not be resolved through mutual discussion then such difference and / or dispute between the Parties shall be referred to sole arbitrator appointed by both the parties in accordance with the Arbitration and Conciliation Act, 1996. The venue of the arbitration shall be Mangalore. The award of the arbitration shall be final and binding between the Parties.

### 12. Limitation of Liability

12.1 To the fullest extent permitted by Applicable Law neither Party nor its affiliates shall be liable for any special, indirect, consequential, or incidental damages (including but not limited to damages for loss of business profits, business interruption, loss of business information, and the like) arising out of this MOU even if either Party has been advised of the possibility of such damages.

### 13. Miscellaneous:

Relationship: No provision of this MOU shall be deemed to constitute a partnership or joint venture between the Parties.

Further, each Party shall inform its employees that they shall not be treated as employees of the other Party for any purpose whatsoever and that they shall not exercise any rights or seek or be entitled to any benefits accruing to the regular employees of the other Party.

No provision of this MOU shall constitute either Party as the legal representative or agent of the other, nor shall either Party have the right or authority to assume, create or incur any liability or any obligation of any kind, express or implied, against or in the name of or on behalf of the other Party except as provided expressly under this Agreement.

### Notices:

Any notice required or permitted to be given hereunder shall be in writing and shall be effectively served.

13.1.1 If delivered personally, upon receipt by the other party;

13.1.2 If sent by prepaid courier service, airmail or registered mail, within seven(7) days of being sent; or

  
Ravi D'Sa  
INISTRATOR  
Medical College Hospital



**DR. MURALI KESHA S.**  
MEDICAL DIRECTOR  
**SPARSHA DIAGNOSTICS**  
Ground Floor, "Vishwas Springfield"  
Opp. Hotel Maya International  
Bendoor, Mangalore - 575 002

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13.1.3 If sent by facsimile or other similar means of electronic communication (with confirmed receipt), upon receipt of transmission notice by the sender.

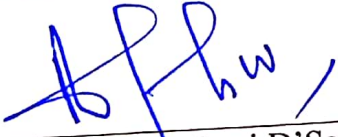

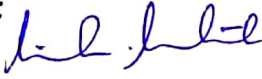
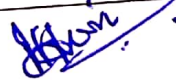

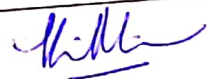
13.1.4 Any notice required or permitted to be given hereunder shall be addressed as given in the title to this MOU.

13.1.5 Any party hereto may change any particulars of its address for notice, by notice to the other in the manner aforesaid.

**Violation of terms:**

The Parties agree that each party shall be entitled to an injunction, restraining order, right for recovery, suit for specific performance, or such other equitable relief as a court of competent jurisdiction may deem necessary or appropriate to restrain the other party from permitting any violation or enforce the performance of the covenants, obligations and representations contained in this MOU. These injunctive remedies are cumulative and are in addition to any other rights and remedies the Parties may have at law or in equity, including without limitation, a right for recovery of the amounts due under this Agreement and related costs and a right for damages.

**IN WITNESS THEREOF** the Parties have through their respectively duly authorized representatives, executed this MOU the day, month and year first hereinabove written.

Signed and delivered by FMMCH Father Muller Medical College Hospital	Signed and delivered by Sparsha SPARSHA DIAGNOSTICS
(Sign) 	(Sign) 
By: Rev. Fr Rudolph Ravi D'Sa Title: Administrator	By: Dr Murali Keshava S Title: Medical Director
Witness1: 	Witness1: 
(Sign)	(Sign) (PEETHAMBAR)
Name: LIDIA PAIS, FINANCE	Name:
Witness 2: 	Witness2: 
(Sign)	(Sign)
Name: JYOTHI PINTO	Name: (DR. KIRANA PAIKOR)

**Dr. MURALI KESHA S.**  
MEDICAL DIRECTOR  
**SPARSHA DIAGNOSTICS**  
Ground Floor, "Vishwas Springfield"  
Opp. Hotel Maya International  
Upper Bendoor, Mangalore - 575 002





தமிழ்நாடு TAMIL NADU

1156  
120218 Anderson Diagnostic  
Services Pvt Ltd.

47AB 279922  
UM SRI BABA  
R. PREMNATH  
STAMP VENDOR  
L.No.8053/B3/07  
HIGH COURT CAMPUS  
CHENNAI - 600 104

### LABORATORY SERVICE AGREEMENT

This Laboratory Service Agreement is entered in to at Chennai on this the day of 20th July 2019.

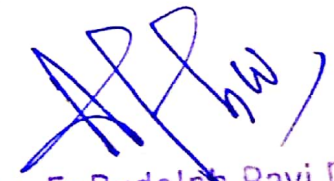
### BETWEEN

**ANDERSON DIAGNOSTIC SERVICES PVT LTD**, also known as **ANDERSON DIAGNOSTICS & LABS**, No 150, Poonamallee High Road, (Opp: Dasaparakash Hotel), CHENNAI- 600084, an **NABL** accredited lab (Reg No: N-0535) represented by **Dr.G.SRINIVASARAMAN** (Director), hereinafter referred to as Party of the **First Part.**

### AND

**FATHER MULLER MEDICAL COLLEGE, MANGALORE, KARNATAKA** Father Muller Road, Kankanady, Mangaluru, Karnataka 575002 herein after called the Party of the **Second Part.**

ANDERSON DIAGNOSTIC SERVICES PVT. LTD.  
  
Director

  
Rev. Fr Rudolph Ravi D'Sa  
ADMINISTRATOR  
Father Muller Medical College Hospital  
Kankanady, Mangaluru-575002



The terms Party of the First Part and Party of the Second Part shall mean and include unless repugnant to the context their respective officers, Administrators and Assigns.

WHEREAS the Party of the First Part is engaged in providing clinical diagnostic services for the last ten years.

WHEREAS the Party of the Second Part is engaged in providing medical care to its patients in the medical field and operating clinical laboratories at its place.

WHEREAS the Party of the Second Part wishes to engage the Party of the First Part to provide clinical diagnostic services upon the terms and conditions set forth in this agreement and the Party of the First Part has also agreed for the same.

In consideration of the mutual covenants hereinafter set forth, the parties agree as follows:

### **1. Terms of Agreement**

The terms of this agreement shall commence on the Effective Date and shall continue for a period of one year, subject to early termination if any. The terms of this agreement may be extended for further periods as per the mutual agreement of both the parties.

### **2. Services**

Upon the request of the Party of the Second Part, the Party of the First Part shall provide to the Party of the Second Part clinical diagnostic services as per Annexure - A

### **3. Pre-processing Requirements:**

3.1 During the period of this agreement, the Party of the Second Part shall under strict hygienic conditions, collect samples at their medical centers, store and label the same for testing to the Party of the First Part strictly in accordance with the Standard Samples Collection Guidelines provided to the Party of the Second Part.

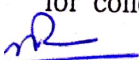
3.2 The Party of the Second Part shall also collect Patients relevant demographic details and clinical details and furnish the same to the Party of the First Part at the time of handing over of the samples.

3.3 The Party of the Second Part shall inform the Party of the First Part about the drawl of samples within 2 hours and the Party of the First Part shall take delivery of the samples from the Party of the Second Part within 2 hours thereafter. The samples shall be kept intact by the Party of the Second Part with the quality materials so that there shall not be any damages to the samples.


3.4 The Party of the Second Part shall provide pre-test and/or post-test counselling strictly in accordance with the Standard Samples Collection Guidelines provided to the Party of the Second Part.

3.5 Both parties shall follow all local and Indian Laws, rules and regulations for collection, disposal of Biohazardous waste materials.

ERSONAL SERVICES PVT. LTD.



Director

  
Rev. Fr. Rudolph Ray  
ADMINISTRATOR  
Father Muller Medical College



#### 4. Processing Requirements:

4.1 The Party of the First Part shall provide the services of collecting the sample and transporting the same from the Party of the Second Part. The Party of the First Part shall facilitate the pick-up of specimen and delivery of reports from the Party of the Second Part and may contract with multiple courier services to perform this assignment.

4.2 The Party of the First Part shall conduct diagnostic test and study of the samples provided by the Party of the Second Part and prepare report regarding the same in the name of the patient and hand over the reports to the Party of the Second Part.

4.3 Critical Reports: The Party of the First Part shall communicate all '**CRITICAL REPORTS**' by phone to the Party of the Second Part, by contacting the designated representative of the Party of the Second Part. However, the Party of the Second Part shall Endeavour to keep abreast of the critical tests out of its own accord. This will further be confirmed by the party of the first part by sending the soft copy of the report.

4.4 Samples which are rejected because of various reasons, including but not limited to, packing, collection methods etc shall be intimated to the Party of the Second Part and the Party of the Second Part shall Endeavour to provide fresh samples at its own costs.

4.5 The Party of the First Part shall maintain required licenses, permits and approvals as mandated under law and shall adhere to Good Laboratory Practice norms.

#### 5. Submission of Reports and Test Results

The Party of the First Part shall use its best efforts to ensure its turnaround time for delivering laboratory test results to Party of the Second Part as mentioned in the Annexure-B. The entire results and records shall be sent by the Party of the First Part in digital format only.

#### 6. Processing Charges

6.1 The Party of the First part shall provide the diagnostic services to the Party of the second Part in accordance with the Pricing Schedule attached as Annexure A

6.2 The Party of the First Part shall raise an invoice on the Party of the Second Part for the test processing charges at the end of every month for all the tests performed during that month in respect of samples sent by the Party of the Second Part. The Party of the Second Part shall pay the invoice in full after appropriate tax deductions at source (if applicable) through cheque only,

  
ANDERSON DIAGNOSTIC SERVICES PVT. LTD.

Director

  
Rev. Fr Rudolph Ravi D'Sa  
ADMINISTRATOR

within a period of 30 days from the date of the bill. No tests or service will be priced or offered below the fair market price.

6.3 Under no circumstances the Party of the First Part shall accept the payment in CASH and payments shall be made through banking channels only i.e. Cheque/Demand Draft/RTGS/NEFT. In case of cheques which are returned unpaid (bounced cheque), payment shall have to be made by demand draft only within 3 working days from the date of intimation to the Party of the Second Part.

6.4 The Party of the Second Part shall raise bill on the Party of the First Part and receive the amount for diagnostic charges as mentioned in annexure A. The Party of the First Part shall not be liable or responsible for any charges that may be billed by the Party of the Second Part on its patients/third parties.

6.5 Both parties agree to mutually indemnify, defend and hold each other from any claim, liability, loss, suit, damages, cost or expense to the extent arising out of or attributable to the negligence, breach of this agreement or willful misconduct by either Party relating to this agreement including but not limited to any third party claim, billing claims brought and any claim brought against either, arising out of or attributable to either for collecting the samples, preprocessing and other matters relating to the same.

## **7. Promotional Materials**

Neither party shall use the name, symbol, logo or any trademark or service mark of the other party in any promotional or advertising materials, nor for any other purpose unless advance written consent has been received from the other party.

## **8. Patient Confidentiality and intellectual property rights**

8.1 Sharing of the intellectual property of the Party of the First Part or price list or any other components as referred to in this agreement is strictly prohibited. Any violation of the same shall attract measures, including termination.

8.2 Both Parties agree that confidentiality regarding the patient's identity and the diagnosis shall be strictly maintained and not divulged to any third party.

## **9. Regulatory Compliance**

Each party represents and warrants that in the performance of its obligations under this agreement, it will comply with all applicable law, rules or regulations. Failure by either party to comply with any applicable law as

  
PERSONAL DIAGNOSTIC SERVICES PVT. LTD.

Director

  
Rev. Fr. Rudolph Ravi D'Sa



required shall be considered as a material breach of this agreement. In the event of a determination that this agreement is not in compliance with any applicable law, then the parties shall negotiate in good faith to bring this agreement into compliance.

#### 10. Termination of the MOU: -

10.1 Either Party may terminate this agreement by giving one month notice in writing. However, both parties shall continue to honor the agreement during the notice period.

10.2 If any of the parties violates any of the terms and conditions of this agreement, the other party shall first intimate the defaulting party to rectify the same within two weeks from the date of intimation. But even thereafter if the same is not rectified, the other party can terminate the agreement with immediate effect by writing a letter to other party.

10.3 This MOU shall be terminated in case of insolvency or bankruptcy of either party.

#### 11. Miscellaneous

11.1 The Party of the Second Part shall not assign any of its rights or obligation under this agreement to any other person/ s without the written consent of the Party of the First Part.

11.2 That this Agreement relates only to the activities submitted hereunder and shall not restrict either of the party from carrying on its normal activities or such other activities undertaken by the parties, independently. Subject to the terms of this Agreement, nothing contained herein shall preclude either party from its normal effort in connection with its activities.

11.3 That neither party shall have any right, power, or authority to create any obligation, express or implied, on behalf of the other except to the extent provided herein.

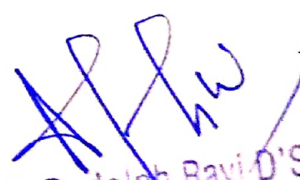
11.4 The Party of the First Part will communicate all relevant details directly to the Party of the Second Part upon introduction of new diagnostic tests. The Sales and scientific team of the Party of the First Part would also help the Party of the Second Part with the relevant specimen requirement, charges, turnaround times, etc.

11.5 Nothing contained in this agreement shall be construed as creating a joint venture, partnership or employment relationship between the parties. Neither party is an agent of the other, and neither party has any authority whatsoever to bind the other party, by contract or otherwise. In witness

For ANDERSON DIAGNOSTIC SERVICES PVT. LTD.



Director




Rev. Fr Rudolph Ravi D'S  
ADMINISTRATOR  
Father Muller Medical College Hosr

whereof, the parties on the first part and the second part have affixed their signatures herein the presence of the following witnesses.

**IN THE PRESENCE OF**

**(WITNESSES):**

For ANDERSON DIAGNOSTIC SERVICES PVT. LTD.  
  
**PARTY OF THE FIRST PART**  
Director

  
**PARTY OF THE SECOND PART**  
**Rev. Fr Rudolph Ravi D'Sa**  
**ADMINISTRATOR**  
Father Muller Medical College Hospital  
Kankanady, Mangaluru-575 002





INDIA NON JUDICIAL

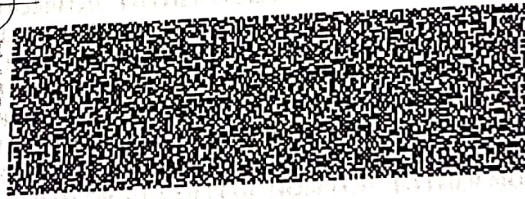
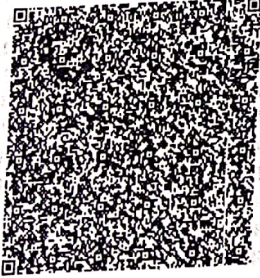
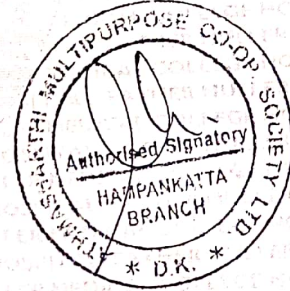
Government of Karnataka

Rs. 100

e-Stamp

Certificate No. : IN-KA26094431855876R  
 Certificate Issued Date : 11-Jan-2019 11:05 AM  
 Account Reference : NONACC (FI)/ kacrsf108/ HAMPANKATTA/ KA-DK  
 Unique Doc. Reference : SUBIN-KAKACRSFL0886810903816521R  
 Purchased by : SRL DIAGNOSTIC PVT LTD  
 Description of Document : Article 12 Bond  
 Description : AGREEMENT  
 Consideration Price (Rs.) : 0  
 (Zero)  
 First Party : FATHER MULLER MEDICAL COLLEGE HOSPITAL  
 Second Party : SRL DIAGNOSTIC PVT LTD  
 Stamp Duty Paid By : SRL DIAGNOSTIC PVT LTD  
 Stamp Duty Amount(Rs.) : 100  
 (One Hundred only)

सत्यमेव जयते



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## MEMORANDUM OF UNDERSTANDING

This Memorandum of Understanding (herein after referred to as "MOU") is made and executed on this date **January 7, 2019** at **Mangalore**

## BY AND BETWEEN

Father Muller Medical College Hospital, Mangalore (a unit of Father Muller Charitable Institutions) situated at Father Muller Road, Kankanady, Mangalore – 575002 represented by Rev Fr. Rudolph Ravi D'sa, Administrator (hereinafter

Rev. Fr. Rudolph Ravi D'Sa



referred to as "FMMCH") which term unless repugnant to the context thereof, shall mean and include its successors-in-interest and permitted assigns, of the FIRST PART

AND

SRL Diagnostics Pvt Ltd its office at Fahir Road, Mangalore duly represented by G S Balasubramanyam Center Head (hereinafter referred to as "SRL") which term unless repugnant to the context shall mean and include its successors and permitted assigns) of the SECOND PART

"FMMCH" and "SRL" are individually and collectively referred to as "Party" and "Parties" respectively.

WHEREAS

1. Father Muller Medical College Hospital Laboratory, a division of Father Muller Medical College Hospital is a clinical laboratory delivering specialized testing facilities in the field of Biochemistry, Hematology, Histopathology and Microbiology.
2. FMMCH offers Inter Laboratory Quality Control specialized pathological diagnostic services on a per-request basis from similar health care facilities.
3. SRL requires services of the type offered by FMMCH.
4. SRL desires to obtain services from FMMCH and FMMCH is willing to provide such services to SRL, in accordance with the terms and conditions set forth within.

Wherefore, it is agreed between the Parties as under:

### 1. Term

- 1.1 This agreement shall be a valid for a period of one year from the date of execution of this agreement. This agreement shall come into effect from January 7, 2019. However either party will renew this agreement for further period of one year with mutual consent.

### 2. Objective

- 2.1 The objective of this MOU is to establish a written document framing a basic understanding under which both the parties shall be governed for conducting diagnostics and monitoring tests on the samples received by FMMCH.

### 3. Scope of Work

- 3.1 During the term hereof or the extended term as the case may be FMMCH shall provide the services to SRL for all the tests requested by SRL. The list of tests annexed to this agreement as **Annexure 1**.



4.1 FMMCH shall conduct tests/investigations as per duly filled request form filled by SRL. The testing and reporting shall be carried out conforming to prevalent high standards of quality.

4.2 FMMCH shall provide reports of tests/ investigations through hard copy by courier.

4.3 FMMCH shall conduct tests/investigations on the basis of samples received from SRL. The sample received from SRL shall be tested and reported within two or three working days under normal circumstances. Reporting timeliness will be in accordance with prevalent quality standards.

## 5. Roles and Responsibilities of SRL

5.1 SRL shall be responsible for proper packing of samples and transportation in defined condition and temperature. Hospital will not be responsible for packing and transportation.

5.2 SRL shall be responsible for sending duly filled test requisition form, patient history, samples packing and labeling at required temperature in good condition to FMMCH for test/ investigations.

5.3 SRL shall make payments to FMMCH for services provided under this MOU within 15 days of receiving the invoices.

5.4 It is the responsibility of SRL to provide additional details requested by FMMCH to conduct the test/ investigation.

## 6. Force Majeure

6.1 Any delay in reporting the test/ investigation shall be subject to Force Majeure, such as unavailability of test kits, failure of test, incomplete patient / test details, problem sample, need for repeat sample/ testing, instrument or machinery breakdown, civil unrest, riots, change in or in the interpretation of laws, strikes, lockout or other labour problems, unavailability of supply, fire or explosion, act of terrorism and other natural calamities. FMMCH would make efforts to mitigate the impact of such Force Majeure conditions and ensure timely testing as feasible and inform SRL accordingly.

## 7. Consideration:

7.1 The billing shall be done on monthly basis starting from 1<sup>st</sup> to 31<sup>st</sup> of each month and SRL undertakes to clear all the outstanding payments within 15 days from the date of receiving the invoices.

7.2 Revision of tariff by FMMCH will be intimated to SRL in writing, upon which the revised rate tariff shall be applicable from the date revision.

## 8. Termination and Consequences of Termination

8.1 Each of the parties makes the following representations and warranties to the other party hereto that the representing party has the full power and unrestricted authority to enter into this MOU. Entering this MOU and performing the obligations hereunder does not conflict with and is not prohibited under the terms of any other agreement, document, law, rule, regulation or court order to which the representing party is subject. Each of the parties has the full power and unrestricted authority to grant the licenses that are granted herein.

**9. Termination and Consequences of Termination**

9.1 This MOU may be terminated on mutual consent or by either party with at least 30 days prior written notice without assigning any reasons.

9.2 All payments due, becoming due and payable to the Parties as on the date of termination, under the terms of this MOU shall continue to be due and payable to the Parties notwithstanding the termination hereof.

**10. Confidentiality:**

10.1 Each Party shall keep secret all Confidential Information, if any, transmitted to it or made available to it by the other Party and shall not pass such Confidential Information on, wholly or partly, to third parties without express written consent of the other Party.

10.2 The Parties shall not disclose the terms of this MOU or make any announcement in respect of the subject matter thereof without prior written consent of the other Party unless the disclosure is required by law or other regulatory authorities. In the event disclosure is required by law, rules or regulations, such disclosure shall be made after obtaining written permission of other party.

10.3 The Confidentiality obligations in this do not apply to disclose information that either Party in writing can prove that:


- i. It was known at the time of disclosure to be free of any obligation to keep it confidential, as evidenced by written records.
- ii. Became generally publicly known through authorized disclosure.
- iii. The information was independently developed without access to or use of any confidential Information, as evidenced by written records, or
- iv. The information was rightfully obtained from a third party who had the right to transfer or disclose it without violation of any confidentially obligations.

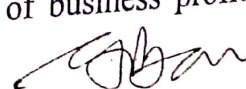
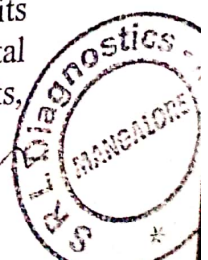
**11. Dispute Resolution and Governing Law**

11.1 In case if any difference or dispute arises between the Parties herein, the Parties shall hold mutual discussions to resolve such difference and / or dispute in an amicable manner for the best interests of both Parties. Parties shall try to resolve the difference and / or dispute within 30 days or such extended time as agreed between the Parties. In case, any difference and / or dispute could not be resolved through mutual discussion then such difference and / or dispute between the Parties shall be referred to sole arbitrator appointed by both the parties in accordance with the Arbitration and Conciliation Act, 1996. The venue of the arbitration shall be Mangalore. The award of the arbitration shall be final and binding between the Parties.

**12. Limitation of Liability**

12.1 To the fullest extent permitted by Applicable Law neither Party nor its affiliates shall be liable for any special, indirect, consequential, or incidental damages (including but not limited to damages for loss of business profits,

  
Ravi D'Sa



business interruption, loss of business information, and the like) arising out of this MOU even if either Party has been advised of the possibility of such damages.

**13. Miscellaneous:**

Relationship: No provision of this MOU shall be deemed to constitute a partnership or joint venture between the Parties.

Further, each Party shall inform its employees that they shall not be treated as employees of the other Party for any purpose whatsoever and that they shall not exercise any rights or seek or be entitled to any benefits accruing to the regular employees of the other Party.

No provision of this MOU shall constitute either Party as the legal representative or agent of the other, nor shall either Party have the right or authority to assume, create or incur any liability or any obligation of any kind, express or implied, against or in the name of or on behalf of the other Party except as provided expressly under this Agreement.

**Notices:**

Any notice required or permitted to be given hereunder shall be in writing and shall be effectively served.

13.1.1 If delivered personally, upon receipt by the other party;

13.1.2 If sent by prepaid courier service, airmail or registered mail, within seven(7) days of being sent; or

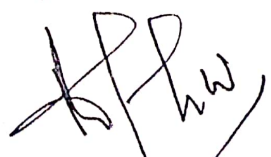
13.1.3 If sent by facsimile or other similar means of electronic communication (with confirmed receipt), upon receipt of transmission notice by the sender.

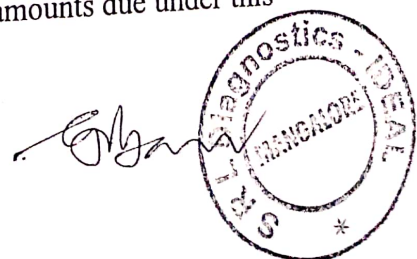
13.1.4 Any notice required or permitted to be given hereunder shall be addressed as given in the title to this MOU.

13.1.5 Any party hereto may change any particulars of its address for notice, by notice to the other in the manner aforesaid.

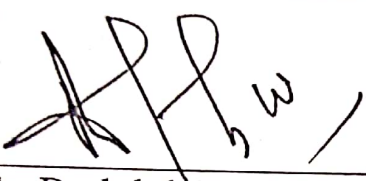

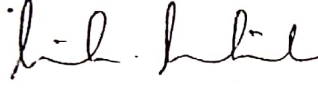
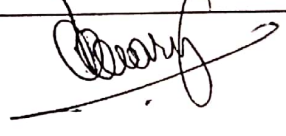

**Violation of terms:**

The Parties agree that each party shall be entitled to an injunction, restraining order, right for recovery, suit for specific performance, or such other equitable relief as a court of competent jurisdiction may deem necessary or appropriate to restrain the other party from permitting any violation or enforce the performance of the covenants, obligations and representations contained in this MOU. These injunctive remedies are cumulative and are in addition to any other rights and remedies the Parties may have at law or in equity, including without limitation, a right for recovery of the amounts due under this Agreement and related costs and a right for damages.

  
Rev. Fr. Rudolph Ravi D'Sa  
ADMINISTRATOR.  
Father Muller Medical College Hospital



IN WITNESS THEREOF the Parties have through their respectively duly authorized representatives, executed this MOU the day, month and year first hereinabove written.

Signed and delivered by FMMCH Father Muller Medical College Hospital	Signed and delivered by SRL For SRL Diagnostics Private Limited Mangalore
(Sign) 	(Sign)  Authorised Signatory
By: Rev Fr. Rudolph Ravi D'sa Title: Administrator	By: G. S. Balasubramanyam Title: CENTER HEAD
Witness1: 	Witness1: 
(Sign)	(Sign)
Name: Ms. LIDIA PAIS, FINANCE	Name: Dr. Chandrayya Achary.
Witness 2: 	Witness2:
(Sign)	(Sign)
Name: JYOTHI PINTO - HRM	Name:

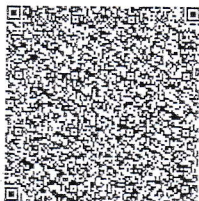




# Government of Karnataka

**e-Stamp**

Certificate No.	: IN-KA70495036503749R
Certificate Issued Date	: 08-Aug-2019 12:41 PM
Account Reference	: NONACC (FI)/ kaksfcl08/ UDUPI1/ KA-UD
Unique Doc. Reference	: SUBIN-KAKAKSFCL0865530844718474R
Purchased by	: BRS HEALTH AND RESEARCH INSTITUTE PVT LTD
Description of Document	: Article 12 Bond
Description	: M O U
Consideration Price (Rs.)	: 0 (Zero)
First Party	: BRS HEALTH AND RESEARCH INSTITUTE PVT LTD
Second Party	: FATHER MULLER MEDICAL COLLEGE
Stamp Duty Paid By	: BRS HEALTH AND RESEARCH INSTITUTE PVT LTD
Stamp Duty Amount(Rs.)	: 100 (One Hundred only)

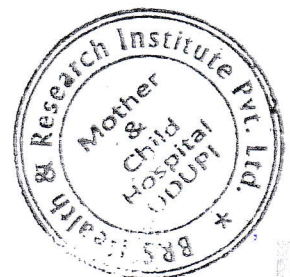
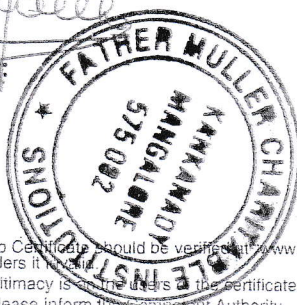


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## MEMORANDUM OF UNDERSTANDING

This Memorandum of Understanding (the 'MoU') is made and executed on 9<sup>th</sup> day of August Month, year Two Thousand and Nineteen 09/08/2019) at Mangalore.

BY AND BETWEEN



**Statutory Alert:**

1. The authenticity of this Stamp Certificate should be verified at "[www.shcilestamp.com](http://www.shcilestamp.com)". Any discrepancy in the details on this Certificate pad as available on the website renders it invalid.
2. The onus of checking the legitimacy is on the users of the certificate.
3. In case of any discrepancy please inform the Competent Authority.

**BRS HEALTH AND RESEARCH INSTITUTE PRIVATE LIMITED**, a private limited company incorporated under the provisions of Companies Act, 1956, having its registered office at No G17 North Block Manipal Centre, Dickenson Road Bangalore – 560042, represented by its Authorized Signatory - **Mr. Prashanth Mallya**.

(Hereinafter referred to as the '**Hospital**', which expression, unless repugnant to the context hereof shall include its holding Company, subsidiaries, associates, affiliates, shareholders and directors) of the **ONE PART**.

**AND**

**FATHER MULLER MEDICAL COLLEGE**, a unit of **Father Muller Charitable Institutions** which is a trust/ society registered under Societies Registration act XXI of 1860, having its office at Mangalore, represented by its Authorized Signatory – **Rev.Fr. Richard Aloysius Coelho**

(Hereinafter referred to as the '**College**', which expression, unless repugnant to the context hereof shall include its associates, affiliates and directors) of the **OTHER PART**.

**WHEREAS**, **Hospital** is engaged in providing specialized medical care services in the areas of maternity, childcare and other allied services with its existing hospital located at Kavi Muddanna Marg, Udupi.

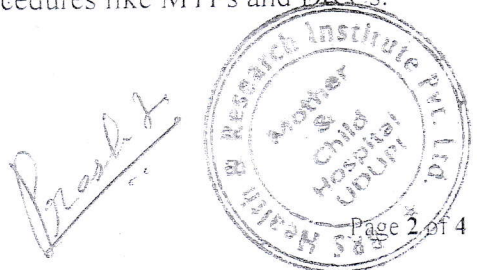
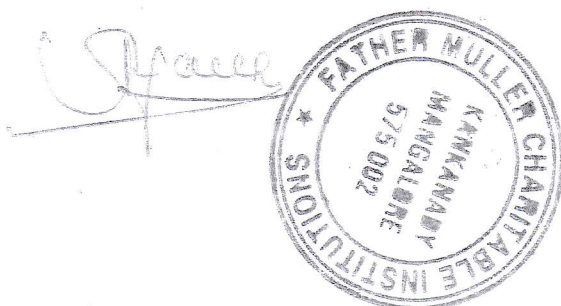
**WHEREAS**, **College** is conducting academic classes for medical students and as part of curriculum of students, College wishes to send Post Graduate students on monthly rotational basis to Hospital.

**WHEREAS**, Hospital and College on mutual acceptance agreed to enter into this MoU to record the terms and conditions of association.

**NOW THIS MOU WITNESSETH** as follows and the parties hereto hereby mutually agree with each other as follows:

## **1. SCOPE**

- a. College will send one second year Post Graduate Student to Hospital on monthly rotational basis for getting experience in obstetrics and gynecologic procedures (including family planning procedures) for their learning under supervision of Hospital consultants and to be part of daily labor room and elective OT.
- b. The postgraduate is expected to take part in labor room activities, procedures, OT cases (obstetric and gynecologic cases), family planning procedure (i.e., concurrent sterilisations, post partum sterilisations, IUCD insertion, PPIUCD insertion and laparoscopic sterilizations) and doing minor procedures like MTPs and D&Cs.



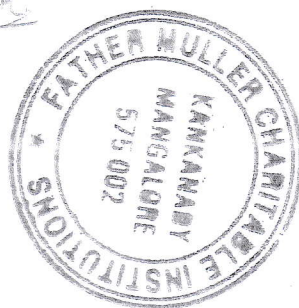


- c. The students will be under supervision and guidance of the duty consultants and shall not be held legally responsible.
- d. The Hospital shall provide Duty Room to students who are coming from College under this MoU during the term of their assignment in Hospital. The College shall ensure that the Students shall follow the rules, regulations and bylaws of Hospital while they are in the Premises of Hospital.
- e. The timing for Students to perform their assignment is 8 am to 8 pm daily (Monday to Saturday and alternate Sundays). Other alternate Sundays shall be considered off duty hours for the students.
- f. The Students attendance shall be recorded on daily basis.
- g. The Students are allowed to have canteen facility at Hospital.
- h. Students shall do daily night rounds by 8pm for wards and inform the cases to the senior consultant.
- i. The Hospital and College shall nominate Single Point of Contact (i.e., the Medical Suprintendent) for implementation of this MoU.
- j. During the term of assignment, the Students shall not be allowed to go out of the Hospital Premises without prior written approval of the Medical Superintendent.
- k. During the period of assignment of Students at Hospital, the Students shall not involve any activities which is in violation of rules of Hospital and Hospital shall not be responsible for any activities they undertake in violation of the rules of Hospital.
- l. The students must maintain a log book mentioning the activities performed during the assignment period with them (i.e. one month) and get the same signed by Medical Superintendent at the end of the assignment period.
- m. Violation of any rules of Hospital by Students shall be treated as breach of terms of this MoU and in such situation Hospital reserves the right to cancel assignment of such student with Hospital. The Hospital shall not be responsible for any accidents which is not attributable to Hospital.

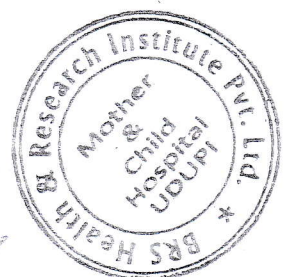
## 2. CONSIDERATION

- a) There is no consideration involved in this MoU.

*[Handwritten signature]*



*[Handwritten signature]*



### 3. TERM & TERMINATION

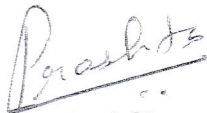
- a) This MoU shall valid for a period of 24 months from the date of signing, unless terminated earlier.
- b) This MoU shall be terminated by either party by giving 30 days prior written notice ("Notice Period") to the other Party.

### 4. REPRESENTATIONS & WARRANTIES

- a) The College represents and warrants to Hospital that, the College has full right to enter into and fully perform this MoU, and entering into this MoU with the Hospital will not in any way infringe upon or violate any applicable law, rule or regulation, any contract with a third party or any rights of any third person.
- b) The College shall share all the information's of students to Hospital along with the necessary supporting certificates.
- c) Each party (Defaulting Party) will indemnify other party and each party shall be responsible for any and all claims, demands, actions, suits or proceedings, liabilities, losses, costs, expenses, taxes, legal fees or damages asserted or incurred against other party by any person or customer on account of acts of commission or omission by the Defaulting Party in connection with this MoU.

IN WITNESS WHEREOF, the parties hereto have signed and executed this Memorandum of Understanding on the date first mentioned hereinabove in the presence of the following witnesses;

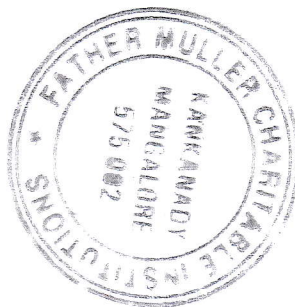
For BRS Health & Research Institute Pvt. Ltd.,

  
Authorized Signatory



For Father Muller Medical College

  
Authorized Signatory







- 1.2. WHEREAS the Cabinet has also agreed to follow the strategies of "Vision 2020 : The Right to Sight" in NPCB as per Plan of Action developed for the country.
- 1.3. WHEREAS NPCB aims to reduce prevalence of blindness by implementing various activities through State and District Blindness Control Societies established in all the districts of the country;
- 1.4. Whereas the NPCB seeks to involve eye care facilities in Government, Non-Government and Private sectors having capacity to perform various activities under National Programme for Control of Blindness;
- 1.5. AND WHEREAS schemes for Non-Government Organizations (hereafter referred as NGO) providing eye care services are implemented as per pattern of assistance approved by the Cabinet;
- 1.6. NOW THEREFORE the signatories of Memorandum of Understanding (MOU) have agreed as set out herein below :

**2. Parties of MOU :**

This MOU is an agreement between District Health and Family Welfare Society (R.) (Blindness Control Division) of Dakshina Kannada of the State of Karnataka; hereafter called District Health and Family Welfare Society (R.) (Blindness Control Division) and Father Muller Charitable Institutions.

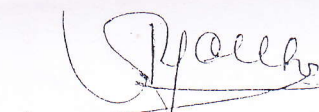
**3. Duration of MOU :**

This MOU will be operative from the date of its signing by the parties and remain in force till 31<sup>st</sup> March 2020. MOU can be renewed through mutual agreement by the parties.

**4. Commitments of NGO :**

Through this MOU the NGO agrees to provide following services under National Programme for Control of Blindness :

Sl.No.	Activities	Yes / No
a)	Screening of population in all the villages / townships in the area allotted to the NGO and preparation of village wise blind registers.	Yes
b)	Identification of cases fit for cataract surgery, motivation thereof and transportation to the base hospital	Yes
c)	Pre-operative examination and investigation as required	Yes
d)	Performance of cataract surgery preferably IOL implantation through ECCE / IOL, Small Incision Cataract Surgery (SICS) or Phaco-emulsification of patients identified in allotted areas, self motivated walk-in cases and those referred by DH & FWS (BCD)	Yes
e)	Post-operative care including management of complications, if any and post-operative counselling regarding use of glasses;	Yes

  
DIRECTOR



f)	Follow-up services including refraction and provision of glasses, if required providing best possible correction.	Yes
g)	Submission of cataract surgery records of operated cases.	Yes
h)	Eye operation for poor and deserving patients other than cataract surgery	Yes

**5. Commitments of District Health and Family Welfare Society (Blindness Control Division) :**  
Through this MOU, the DH & FWS (BCD) agrees to provide following support to participating NGO to facilitate service delivery :

Clause	Clause of Agreement	Yes / No
5.1	Issue Certificate of Recognition about participation in NPCB	Yes
5.2	Undertake random verification of operated cases not exceeding 5% before discharge of patients;	Yes
5.3	Sanction cost of free cataract operations performed by the NGO as per GOI guidelines indicated in para 6 below within one month of submission of claim along with Cataract Surgery Records;	Yes
5.4	Make payment of the sanctioned amount to the NGO on monthly/quarterly basis;	Yes
5.5	Regularly disseminate literature, guidelines or any other relevant information to participating NGO)	Yes

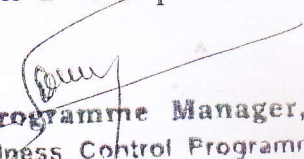
**6. Grant-in-aid to NGO for the Scheme other than Cataract Surgery :**

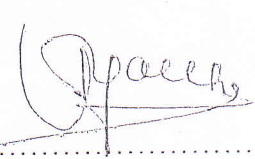
1.	Cataract Surgery	Rs. 2,000.00
2.	Diabetic Retinopathy	Rs. 2,000.00
3.	Childhood Blindness	Rs. 2,000.00
4.	Glaucoma	Rs. 2,000.00
5.	Keratoplasty	Rs. 7,500.00
6.	Vitreoretinal Surgery	Rs.10,000.00

**7. Termination of MOU :**

Commitments agreed to by the Parties are meant for prevention and control of blindness and therefore MOU should generally not be suspended or terminated. However, both parties can decide to suspend or terminate the MOU.

Signed this day, the 2<sup>nd</sup> of April 2019

  
Dist. Programme Manager,  
Dist. Blindness Control Programme  
Dakshina Kannada District  
For and on behalf of,  
District Health and Family Welfare Society (BCD)

  
DIRECTOR  
Father Muller Charitable Institution  
FR. MULLER ROAD  
MANGALORE-575 002