Regd. No.: 1430
Date : 31/5/2021

INDIA NON JUDICIAL

Government of Gujarat

Certificate of Stamp Duty

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Description of Document	:	Article 5(h) Agreement (not otherwise provided for)
Description	:	MOU FOR ENROLMENT WITH RRN
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First Party	:	PULMOCARE RESEARCH AND EDUCATION FOUNDATION
Second Party	:	SUMANDEEP VIDYAPEETH
Stamp Duty Paid By	:	PULMOCARE RESEARCH AND EDUCATION FOUNDATION
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B.S. DAFTARY
VADODARA

Attested CTC

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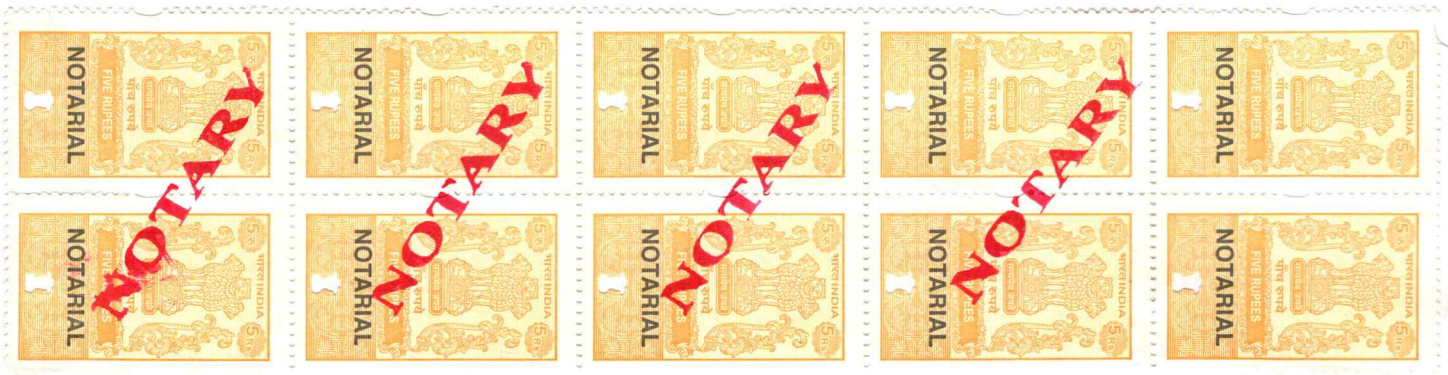
Vice-Chancellor
Sumandeep Vidyapeeth
An Institution Deemed to be University
Vill. Piparia, Taluka: Waghodia
Dist. Vadodara-391 760. (Gujarat)



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NOTARY
NAME
BHARAT S. DAFTARY
AREA
VADODARA DIST.
REGD. NO. 3703/06
GOVT. OF INDIA

SUMANDEEP VIDYAPEETH

Memorandum of Understanding for Enrolment with RRN

This Memorandum of Understanding ("**MoU**") is made and entered into on this 31/05/ 2021 ("**Effective Date**") by and between:

Pulmocare Research and Education (PURE) Foundation which is a not-for-profit section 8 company through its **Respiratory Research Network** division (located at 1st Floor FAITH Centre, Survey No. 232, Sakore Nagar, Viman Nagar Pune, India, Maharashtra - 411014 (hereinafter referred to as **RRN**); and

Dr Arti Shah a medical professional, an Indian citizen, and having a permanent residence at 39/40 Sadhyanand Society, Harni Ring Road, Vadodara, 390022 (hereinafter referred to as the "**Investigator**") and,

Sumandeep Vidyapeeth an institution Deemed to be University an institute registered under U/s.3 of UGC act 1956 and having its registered office at At & Po. Piparia, Ta. Waghodia Vadodara 391760 (hereinafter referred to as the "**Institute**")

RRN, the Investigator and the Institute may hereinafter be collectively referred to as the "**Parties**" and individually as a "**Party**".

WHEREAS:

A. **PURE** Foundation is a state-of-the-art research institute dedicated for research and education in the field of chronic respiratory diseases with focus on Obstructive Airways Disease. It conducts community based epidemiological studies, and academic clinical research.

B. RRN, a division of PURE Foundation, is a non-profit network of doctors dedicated to research in respiratory medicine which has its wide reach across India. RRN conducts large scale multi-centre academic research in respiratory medicine in India. It brings together the expert doctors in the field of respiratory medicine from all over the country under one platform to facilitate knowledge sharing and research. RRN persuades the network investigators to translate new research ideas into multi-centre studies so that the data generated has a good geographical representation of Indian population.

C. The Investigator is a Doctor, who is attached with the Institute, wishes to enrol into a research project and responsible for the patient care, taking Institutional Ethics Committee approval, informed consent and collection of data from patient at a participating site or has

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initiated a research project and has sought RRN for Assistance (as defined below) towards performing the Research Project (as defined below) and RRN has gladly agreed to provide Assistance to the Investigator.

D. The Institute based on the request from the Investigator & RRN has agreed to give its consent for the Investigator & RRN to conduct the Research Project.

E. Based on the request and representations and warranties of the Investigator & RRN, the Parties hereby agrees to collaborate each other, in accordance with the terms and conditions contained herein.

NOW THEREFORE, the Parties agree as follows:

Definitions:

"Affiliate" means any entity that controls, is controlled by or is under common control with such Party, where "control" means the possession, directly or indirectly, of the power to direct or cause the direction of the management and policies of such entity, through ownership of more than fifty percent (50%) of the outstanding voting securities or other ownership interests, by contract or otherwise.

"**Assistance**" means assistance in protocol designing and document preparation, study conductance, data management, site selection and meeting logistics, initiation and training, material procurement, study archival and close out and other coordination related support which RRN has agreed to provide to the Investigator time to time.

"**Causes**" shall have the meaning as set out in section 7.

"**Confidential Information**"

- Shall mean and includes without limitation, any information pertaining to the Purpose disclosed, either directly or indirectly, in writing or orally or by inspection of tangible objects (including without limitation documents, prototypes, samples, plant and equipment) during the course of the discussions/negotiations for the Purpose (the "Discussions") by one Party (the "Disclosing Party") to the other party (the "Receiving Party") including (a) confidential and proprietary trade secrets of the Disclosing Party and/or all other information belonging or relating to the Disclosing Party's business that is not generally known; (b) the Disclosing Party's products, processes, methodologies, systems techniques, programs, data, software, know-how, documentation of developed systems, improvements, developments, techniques, business or marketing plans, strategies, forecasts, licenses, ideas, concepts, form, format, graphics, prices or lists of the Disclosing Party, business and financial affairs, personnel matters, operating procedures, organization responsibilities, marketing matters and any policies or procedures; (c) Proprietary Information as defined hereinafter and (d) the terms and conditions of this Agreement. The Confidential Information will also include any information disclosed by the Disclosing Party to the Receiving Party in relation to the

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Purpose prior to the acceptance of the confidentiality obligations contained in this Agreement.

- Shall exclude information that: (i) can be shown with documents as already known to the Receiving Party at the time that it is disclosed to the Receiving Party; (ii) is in or comes to public domain through no fault, wrongful act or breach of this Agreement on the part of the Receiving Party; (iii) has been independently developed by the Receiving Party without breach of this Agreement or infringement of the proprietary rights of Disclosing Party; (iv) has been rightfully received from a third-party without restriction on disclosure and without breach of this Agreement; (v) has been approved in writing for disclosure by the Disclosing Party; (vii) is required by law or any government agency to be disclosed, provided however, that prior to such disclosure, the Receiving Party shall provide the Disclosing Party with written notice of any such request or requirement in order to enable the Disclosing Party to seek a protective order or other appropriate remedy; (viii) lawfully in the possession of the Receiving Party prior to receipt from the Disclosing Party.

"**Intellectual Property Rights**" means any patent, copyright, trademark, service mark, service name, trade name, internet domain name, brand name, trade dress, label, logo, know-how, technical and non-technical information, trade secret, formulae, technique, sketch drawing, model, invention, design, specifications, processes, apparatus, equipment, database, research, experimental work, development, software programs and applications, software source documents and third-party license

"Project Coordinator" shall have the meaning as set out in section (e).

"**Research Project**" shall mean the research study in the field of respiratory medicine for which the Parties are hereby collaborating each other.

1. Appointment, Scope and Rights:

a) The Investigator shall initiate and perform the Research Project and undertake all responsibilities for the same and RRN shall provide timely Assistance to the Investigator as specified in Annexure A.

b) Investigator represents that the Investigator has the professional knowledge and experience required for performing Research Project and RRN also represents that it has the required experience, research facilities and professional expertise to provide timely Assistance to Investigator on the Research Project.

c) RRN's participation will be limited solely to providing timely Assistance as required, as per the terms and conditions laid down under this MoU.

d) The Investigator hereby agrees to grant to RRN access and right to use any data / results findings / observations / analysis or any other information that is derived from, either directly or indirectly, from the Research Project conducted by the Investigator.

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e) During the course of the Research Project, the Investigator shall communicate with RRN's Project Coordinator. The Project Coordinator shall be responsible for coordinating with the Investigator with regards to the timely Assistance to be provided and the use of the same. RRN shall ensure that the Project coordinator shall always be available for the same.

f) The Investigator shall comply with all applicable laws during the course of performing the Research Project. RRN shall not be liable in any way for any breach of the same by the Investigator. The Investigator shall be solely responsible for any negligence in performing the Research Project, breach of applicable laws, violations of third-party Intellectual Property Rights, personal injury or death and misuse, loss and medical negligence.

g) The Investigator has represented to RRN that the Research Projects shall be completed within the provided time-frame for every project where participation has been agreed upon by the Investigator. In the event of any actual or anticipated delay, the Investigator shall intimate RRN of the same in writing 30 days before the expiry of the said time-frame and thereafter the Parties shall mutually discuss on the revised timelines or any other measures as they may deem fit.

h) The Investigator agrees that it shall be his sole responsibility to procure the funding for the Research Project unless there is a provision of funding arranged by principal investigator or RRN from external agencies by means of a research grant for the project. RRN shall not be responsible for providing any financial assistance to the Investigator/study site. Any cost of printing or translation shall be undertaken by RRN provided the same has been pre-approved in writing by the Project Coordinator.

i) Investigator/institute shall ensure that the Patient Data being transferred to the RRN does not contain any Patient-identifiable Data or Personal Data and shall be as Anonymised Patient Data.

2. Confidentiality

a) The Parties may from time to time disclose to each other by virtue of this MoU, certain Confidential Information.

b) The Parties agree not to use Confidential Information for any purpose other than for performing the Research Project as mutually agreed between the Parties and in accordance with the terms and conditions in this MoU. The Parties shall not disclose Confidential Information to any third party, without the prior written consent of the other Party.

c) Where any Party needs to disclose Confidential Information or data to any other investigator or person (on a need-to-know basis), the Receiving Party shall ensure that such receiving person first agrees, in writing, to be bound by terms of confidentiality as laid out in this MoU.

d) No Grant of Rights: Nothing in this MoU nor any disclosure of information by either Party before or after its execution, shall operate to confer any Intellectual Property Rights on the

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other Party, nor be effective to license or transfer to the other Party any right, title or interest in the RRN's process or information. Further, the Parties hereby undertakes not to claim any rights in the Confidential Information shared by the Disclosing Party under the terms of this MoU.

e) The Parties do hereby agree and confirm that it shall, upon the early termination or expiry of this MoU, immediately deliver to the Disclosing Party all Confidential Information, which are in its possession or control, without retaining any copy thereof. The obligations of confidentiality and non-use shall survive for 5 (five) years after the expiry or earlier termination of this MoU.

3. Intellectual Property:

Any Intellectual Property Rights arising from or in relation to any Assistance to the Investigator by RRN under the terms of the MoU, including but not limited to all records, reports, deliverables, shall be jointly owned by the Investigator and RRN.

4. Indemnity:

a. Investigator Indemnity:- Investigator shall indemnify and hold RRN its Affiliates and/or their respective Representatives and assigns harmless against all notices, claims, demands, action, suits or proceedings given, made or initiated against RRN on account of or arising out of any and all liabilities, damages, injuries, cause of action and expenses including attorney's fees suffered or incurred by RRN for (a) breach of responsibility of Investigator; (b) loss or damage caused to Investigational Product and Study Materials; (c) willful negligence, misconduct and misrepresentation (d) breach of representation and warranties and confidentiality obligations under this Agreement.

b. RRN Indemnity:- RRN shall indemnify and hold Investigator harmless against all notices, claims, demands, actions, suits or proceedings given, made or initiated against all notices, claims, demands, action, suits or proceedings given, made or initiated against Investigator on account of or arising out of any and all liabilities, damages, injuries, cause of action and expenses including attorney's fees suffered or incurred by Investigator for (a) breach of responsibility of RRN; (b) loss or damage caused to Investigational Product and Study Materials; (c) willful negligence, misconduct and misrepresentation (d) breach of representation and warranties and confidentiality obligations under this Agreement.

5. Term and Termination:

a) The term of this MoU shall commence on the Effective Date and remain in force for a period of five (5) years after which the MoU shall stand terminated.

b) The Parties shall, at its discretion, be entitled to terminate this MoU at any time, by serving a prior written notice of thirty (30) days to the other Party. Upon such termination, the Parties

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shall mutually cooperate with each other and immediately return all data and material which it has received during the Research Project

c) The Parties shall be permitted to terminate this MoU, effective immediately, should the other Party:

- breach any of the Confidentiality and/or Intellectual Property Rights obligations contained in this MoU;
- breach any regulatory and/or statutory requirement with regards to the clinical trial to be performed by them.

6. Data Provision

- Investigator shall only provide Patient Data to RRN which passes the following tests, unless agreed otherwise by the Parties:
- the Patient whose Patient Data has been provided meets the individual studies inclusion criteria and exclusion criteria as defined by the study protocol.
- Investigator shall provide Patient Data that contains at least ninety percent (90%) of the Core Variables. In the event that Patient Data provided by Investigator contains less than 90% of the Core Variables, RRN may choose not to include such Patient Data in the analysis, at its sole discretion.

7. Security and Passwords

The Parties shall ensure that any Patient Data they hold is kept secure and in an encrypted form, and shall use all reasonable security practices and systems applicable to the use of the Patient Data to prevent, and take prompt and proper remedial action against, unauthorised access, copying, modification, storage, reproduction, display or distribution of the Patient Data.

Where either Party uses security features in relation to the Patient Data (wholly or in part), the security features must, be kept confidential and not lent, shared, transferred or otherwise misused by either Party.

If either Party:

- becomes aware of any unauthorised or unlawful processing of any Patient Data or that any Patient Data is lost or destroyed or has become damaged, corrupted or unusable;
- becomes aware of any security breach; or learns or suspects that any security feature has been revealed to or obtained by any unauthorised person, that Party shall, at its own expense, promptly notify the other Party and fully co-operate with the other Party to remedy the issue as soon as reasonably practicable.

8. Publication

a) RRN holds right to publish the interim/full data at national and international conferences and peer reviewed journal.

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b) If at any time the Investigator wishes to report or publish or make available the data, results or any report of the Research Project conducted under or in connection with the Research Project to any third party or publish in any journal, book or magazine, the Investigator shall seek prior written consent of RRN, which consent shall not be unreasonably withheld. Accordingly, the results of the Research Project may be published in medical journals or presented at a public forum such as conferences after RRN's written confirmation and after RRN has been provided a reasonable opportunity to review such publication and satisfying itself that such publication will not compromise IPR and/or confidentiality associated with the Research Project.)

c) In all publications RRN's support of the Research Project shall be acknowledged unless the law provides otherwise. The specific details of the publication and the format of acknowledgement of RRN's support will be mutually agreed between the Parties.

d) Either Party may use, for its own internal purpose, all information and data generated in course of the Research Project.

e) Investigator shall have all rights, title and interest in the Patient Data and the RRN shall seek prior written consent before any such publication. Investigator shall not be entitled to independently publish results relating to the study objectives and RRN priorities. Once the RRN has made such publication public, Investigator shall be entitled to publish such results using its site Patient Data.

f) Every project will have a minimum number of cases for authorship which will be mentioned during the call/invitation for participation of the respective study.

9. Force Majeure:

Neither Party hereto shall be liable for any delay or default in such Party's performance hereunder, if such default or delay is caused by events beyond such Party's reasonable control including, but not limited to, acts of God, regulation or law or other action or failure to act of any government or agency thereof, war or insurrection, civil commotion, earthquake, fire, flood or storm (**"Causes"**); provided however, that the Party seeking relief hereunder shall promptly notify the other Party of such Causes beyond such Party's reasonable control. The operation of this MoU shall be suspended during the period in which the above reasons continue.

10. Payment

a) The Parties consider that the obligations on each are considered equal mutual consideration and no fee shall be paid or is owing from one Party to the other Party under this Agreement.

b) Investigator indemnifies RRN against any and all claims arising from an its institution. Any claim for payment or reimbursement will not be accepted unless until agreed by the parties in advance i:e before the start of the respective study.

NOTARY BHARAT S. DAFTARY ADVOCATE REG. NO. 3703/06 VADODARA DIST. GOVT. OF INDIA

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11. Notices:

Any notice given under this MoU shall be in writing and signed by or on behalf of the Party giving it and may be served by delivering it personally or sending it by pre-paid recorded delivery or registered post or fax to the address and for the attention of the relevant Party. Any change in address shall be notified by a Party to the other.

Any such notices be deemed to have been received;

-if delivered personally at the time of delivery;

-in the case of registered airmail, pre-paid recorded delivery or registered post-upon receipt;

-in the case of fax, at the time of transmission.

The addresses and fax number of Parties for the purpose of any written notice is as follows:

If to RRN:

If to RRN:

Address: RRN Office, 1st Floor FAITH Centre, Survey No. 232, Sakore Nagar, Viman Nagar Pune, India, Maharashtra - 411014

Attention: Dr. Shrikant Pawar

Email: dcc@rrn.net.in

If to Investigator:

Name: Dr. Arti D. Shah

Address: Sumandeep Vidyapeeth, Piparia, Waghodia, Vadodara, 391760, India

Email: artidhawal76@gmail.com

12. Governing Law and Jurisdiction:

Any dispute or claim arising out of or in connection with this MoU, or the breach, termination or invalidity thereof shall be governed exclusively by the laws of India with exclusive jurisdiction of courts of Pune. Each Party shall make efforts to settle any dispute arising hereunder in an amicable manner within thirty (30) days; failing which such dispute shall be governed by the exclusive jurisdiction of courts of Pune. Notwithstanding the above, each Party shall be entitled to urgent interim and interlocutory relief from a court of competent jurisdiction.

13. Assignment:

Neither this MoU nor any rights or interest herein may be assigned or transferred by the Parties without the express written consent of other Party.

14. Independent Contractor:

No provision of this MoU shall be deemed to constitute a partnership between the Parties and except as stated otherwise in this Memorandum, neither Party shall have any right or authority to bind the other as the other's agent or representative and neither Party shall be deemed to be the agent of the other in any way.

SUMANDEEP VIDYAPEETH

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15. Entire MoU:

This MoU and the documents referred to herein constitute the entire agreement and understanding of the Parties and supersede any previous MoU or arrangement between the Parties relating to the subject matter of this MoU.

16. Waiver:

No waiver of any term or provision of this MoU or forbearance to enforce any term or provision by either Party shall constitute a waiver as to any subsequent breach or failure of the same term or provision or a waiver of any other term or provision of this MoU.

17. Modification:

This MoU may only be amended by the Parties mutually in writing.

18. Severability:

In the event that any provision of this MoU becomes or is declared by a court of competent jurisdiction to be illegal, unenforceable or void, this MoU shall continue in full force and effect without the aforesaid provision; provided that no such severability shall be effective if it materially changes the economic benefit of this MoU to either Party.

19. Costs:

Each of the Parties shall pay any costs and expenses incurred by it in connection with this MoU.

20. Counterparts:

This MoU may be executed in counterpart, each of which shall be deemed an original, but both of which together shall constitute one and the same instrument.

NOTARY
NAME
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AREA
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REGD. NO. 3703/06
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SUMANDEEP VIDYAPEETH

31/05/2021

IN WITNESS WHEREOF, the Parties have caused this MoU to be executed by their duly authorized representatives to be effective as of the Effective Date. Signed by investigator, institute and for and on behalf of **PURE Foundation** through its **Respiratory Research Network.**

1. For investigator

Authorized Signatory

Name of Investigator: Dr. ARTI SHAH

DR. ARTI D. SHAH
(DTCD, DNB)
Professor,
Dept. of Respiratory Medicine & Chest R.C.,
Sumandeep Vidyapeeth, Piparia, Waghodia.

Stamp with Registration number:

2. For institute

Authorized Signatory

Name of the authorized person of the institute: Dr. Neeraj Deshpande

Stamp

3. For PURE foundation

SUNDEEP SANTOSH SALVI
Digitally signed by SUNDEEP SANTOSH SALVI
Date: 2021.04.06 21:06:50 +05'30'

Authorized Signatory

Director, PURE foundation

Attested CTC
29/11/2022.
Vice-Chancellor
Sumandeep Vidyapeeth
An Institution Deemed to be University
Vill. Piparia, Taluka: Waghodia.
Dist. Vadodara-391 760. (Gujarat)

Stamp

NOTARY
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AREA
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REGD. NO. 3703/06
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ATTESTED
BHARAT S. DAFTARY
NOTARY

BHARAT S. DAFTARY
Advocate & Notary Public
GF/32, Paradise Complex,
Sayajigunj, Vadodara-05.
M.: 98988 22538, 79842 98397

Signature and Date:

31/05/2021

Annexure A

Details of Assistance Provided by RRN:

- Assisting in protocol designing and document preparation time to time.
- Identifying and appointing a Project Coordinator.
- Site selection and Investigator meeting arrangements
- Site Initiation and training
- Material procurement and shipping
- Monitoring and Audits
- Data analysis
- Study Archival and close out
- Publication assistance

Responsibility of Investigator:

- To adhere to the protocol
- Ensure availability of infrastructure and resources to conduct good quality clinical trial.
- Obtaining Ethics Committee approval at their site
- Active participation towards hypothesis generation, protocol writing, fund raising and publications for the study proposed by the investigator
- Ensuring timely patient recruitment and data transfer to RRN.
- Resolving data queries and ensuring data integrity at their site.
- Paper writing for the proposed project after data analysis by RRN.
- Acknowledging RRN and other contributing investigators in all publications or information disseminations (at meeting/conferences) where data is being presented/referred.

NOTARY NAME BHARAT S. DAFTARY AREA VADODARA DIST. REGD. NO. 3703/06 GOVT. OF INDIA

SUMANDEEP VIDYAPEETH

Attested CTC

30/11/2023

Vice-Chancellor
Sumandeep Vidyapeeth
An Institution Deemed to be University
Vill. Piparia, Taluka: Waghodia.
Dist. Vadodara-391 760. (Gujarat)

31/07/2024