INVESTIGATOR SPONSORED
NON-INTERVENTIONAL RESEARCH AGREEMENT

(Global Single Site - Funding Only Non-Interventional)

This Agreement is entered into as of the last date on the signature page hereof, by and between MANUEL PEREZ FOUNDATION, with its address at Av. Gral. Flores 2125, Montevideo, Uruguay 11800, hereinafter called "Institution," and MERCK SHARP & DOHME LLC, with its address at 126 East Lincoln Avenue, P.O. Box 2000, Rahway, New Jersey 07065 USA, hereinafter called "MSD."

Principal Investigator (named in Article 2 below) and Institution desire to sponsor and conduct a non-interventional study through certain clinical research (the "Study"). MSD, consistent with its commitment to clinical research, wishes to provide certain support to Institution on the terms and conditions described in this Agreement. The parties hereto agree as follows:

1. Scope of Work

The Institution and Principal Investigator (named in Article 2 below) shall perform the Study in accordance with the terms of this Agreement and the final protocol including as it may be amended in accordance with the terms of this Agreement, for the Study entitled "Observational, descriptive, prospective, longitudinal study of the characteristics, outcome, and follow-up after hospital discharge of children with pneumonia complicated by pleuropulmonary suppuration and/or pulmonary necrosis" (the "Protocol") MISP Database number 101798, which has been accepted by MSD in writing and incorporated into this Agreement by reference. Institution certifies that, to its best knowledge, its facilities and patient population are adequate to perform the Study contemplated by this Agreement and the Protocol. Institution and Principal Investigator agree that all aspects of the Study will be conducted in conformity with all applicable laws and regulations, including the International Council for Harmonisation of Technical Requirements for Pharmaceuticals for Human Use (ICH) - Guideline for Good Clinical Practice and other generally accepted standards of good clinical practice. Institution and Principal Investigator further agree not to conduct any research activities which are contrary to the provisions of the Protocol or outside the scope of the Protocol. Principal Investigator (or Institution) will undertake the Study as the legal sponsor of the Protocol and will fulfill the requisite sponsor duties and obligations in conducting the Study. Institution and Principal Investigator agree that Institution is the sole research site conducting this Study.

2. Principal Investigator

Institution's principal investigator is Dr. Elizabeth Assandri ("Principal Investigator"). Principal Investigator will be responsible for the direction and supervision of all Study efforts, in accordance with the Protocol and this Agreement. Principal Investigator and Institution shall perform all of the research contemplated herein through fully trained and competent Study Staff (as defined below) having a skill level appropriate for the tasks assigned to them and shall ensure that all Study Staff (as defined below) comply with the terms of this Agreement and the Protocol. "Study Staff" means (i) employees, officers, and directors of Institution, including without limitation the Principal Investigator, and (ii) any agents, contractors or other third parties approved by MSD in writing in accordance with Article 13. Principal Investigator and Institution will ensure that any investigators

and any other staff comply with the terms of this Agreement and the Protocol. In the event that Principal Investigator leaves or is removed from the Institution, then Institution shall, within ten (10) days of becoming aware of such departure by Principal Investigator, provide written notice of such event to MSD. Any successor to Principal Investigator must be approved, in writing, by MSD and such successor shall be required to agree to all the terms and conditions of the Protocol and this Agreement and to sign each such document as evidence of such agreement (although failure to so sign will not relieve such successor from abiding with all the terms and conditions of the Protocol and this Agreement).

Institution represents and warrants that it will not use in any capacity, in connection with any services to be performed under this Agreement, any individual who has been debarred, disqualified as a testing facility, disqualified as a clinical investigator or excluded from a healthcare program, pursuant to any applicable laws or regulations, including the United States Federal Food, Drug and Cosmetic Act.

Institution agrees to immediately inform MSD in writing if any person who is performing services hereunder is debarred, disqualified or excluded or if any action, suit, claim, investigation or legal or administrative proceeding is pending, or, to the best of Institution's knowledge, is threatened, relating to the debarment, disqualification or exclusion of Institution or any person performing services hereunder. Principal Investigator represents and warrants that no action, suit, claim investigation or legal or administrative proceeding is pending or threatened relating to Principal Investigator's debarment, disqualification or exclusion and Principal Investigator agrees to immediately inform MSD in writing if any such action, suit, claim, investigation or legal or administrative proceeding is threatened or commenced for Principal Investigator's debarment, disqualification or exclusion. If Institution is not owned or controlled by the government, Institution represents and warrants that Institution is not owned by 50% or more by a person listed on the U.S. Treasury Department's List of Specially Designated Nationals and Blocked Persons (the "SDN List") (https://www.treasury.gov/ofac/downloads/sdnlist.pdf) or U.S. Treasury Department's Office of Foreign Asset Controls "OFAC" Consolidated Sanctions List (https://www.treasury.gov/resource-center/sanctions/SDN-List/Pages/consolidated.aspx). Institution further represents and warrants that Institution shall notify MSD in writing immediately if Institution becomes owned by 50% or more by a person listed on the SDN List.

Institution and Principal Investigator agree that they will, to the extent required by applicable law, obtain an appropriate consent from any individual for whom Institution and Principal Investigator will disclose personal information to MSD for MSD to use and disclose as needed for purposes related to the performance of this Agreement and any related health authority or regulatory inspection or request.

The Principal Investigator represents and warrants that, other than the following individuals and their respective organizations (if any):

_____

_____,

Principal Investigator or members of Principal Investigator's immediate family relatives (including married and unmarried spouse; siblings, children, parents, grandparents) are not employed or engaged, whether paid or unpaid, in any of the following in a capacity that could allow the individual to influence the business of the MSD or its affiliates: (a) as government official (including a

relationship with a governmental official which could cause the official to influence the business of the MSD); (b) on or serving in an official advisory capacity to any reimbursement committee, pricing committee, drug approval committee, formulary or similar committee; (c) in any other governmental position, including a position in an international governmental health organization, such as the WHO (World Health Organization) or UNICEF. Principal Investigator will advise the MSD to the extent Principal Investigator or Principal Investigator's immediate family member's status described in the prior sentence changes during the term of this Agreement.

Without waiving confidentiality provisions, Principal Investigator agrees to disclose the nature of Principal Investigator's relationship with MSD to the entities listed above or any other such entities and comply with any conflict of interest policies of such entities. In addition, Principal Investigator will as directed by MSD: (a) refrain, during the term of this Agreement and for a period of one (1) year thereafter, from participating in decisions that could impact MSD's or its affiliates business; (b) seek prior approval from such entity before entering into this Agreement; and/or (c) disclose the business relationship with the MSD to such entity prior to each time participating in any decision which could have an impact on the business of MSD or its affiliates.

3. **Clinical Trial Approvals**

A. Institution shall be responsible for obtaining the following:

(i) any regulatory approvals required for the performance of the Protocol;

(ii) approval of the Protocol, any informed consent relating to the Study and advertisement, if any, pertaining to the enrollment of subjects in the Study by the appropriate Ethics Committee ("EC") prior to beginning any Study on human subjects;

(iii) an informed consent which complies with all applicable laws and regulations signed by or on behalf of each human subject prior to the subject's participating in the Study that does not reference MSD as the sponsor or make any representations on behalf of MSD but may list the type of support provided by MSD under this Agreement; and

(iv) an EC approved data privacy authorization to use and disclose personal health information (either incorporated into the informed consent form or in a separate document) which complies with all applicable laws and regulations signed by or on behalf of each human subject prior to the subject's participating in the Study.

B. In the event the EC requires changes in the Protocol, MSD shall be advised in advance and all modifications to the Protocol must be approved in advance by MSD. Institution and Principal Investigator shall not modify the Study described in the Protocol once finalized and after approval by the EC without the prior written approval of MSD.

C. Principal Investigator and Institution shall ensure that EC approval shall be maintained current at all times and in the event that the Study continues beyond the period of the initial EC

approval, shall ensure that appropriate periodic EC re-approval is obtained without lapse in approval status and provide MSD with EC re-approval date. In the event that EC approval lapses, becomes suspended, or withdrawn, Principal Investigator or Institution shall notify MSD within twenty-four (24) hours of that event and EC's reasons for approval lapse, suspension or withdrawal.

4. **Term of Agreement**

The term of this Agreement shall commence on the last date of the signature page hereof and shall continue in effect, unless earlier terminated in accordance with Article 5, until the Study is completed and all final Study documentation, including but not limited to Study manuscripts, required to be provided under the Protocol and this Agreement is received and accepted by MSD. If at any time Institution or Principal Investigator have reason to believe that the Study will not be initiated or completed as per the schedule initially anticipated and agreed upon by the parties, MSD will be advised, in writing, of the reason(s) and length of additional time required to commence or complete work, and this Agreement may be terminated by MSD as provided in Article 5.

5. **Termination**

A. MSD or Institution may terminate this Agreement by giving thirty (30) days written notice to the other party. Notwithstanding the foregoing, in the event MSD or Institution believes that immediate termination is necessary due to its evaluation of risks to enrolled research subject(s), MSD or Institution may terminate this Agreement immediately.

B. Either party may terminate this Agreement immediately upon written notice to the other party if the other party breaches any of its material obligations under this Agreement and such breach, if capable of being cured, is not cured within thirty (30) days of written notice of such breach.

C. In the event of any termination or expiration of this Agreement (including but not limited to completion of the Study):

(i) upon providing or receiving a notice of termination of this Agreement, Institution shall stop enrolling patients in the Study and shall in accordance with MSD's instructions cease conducting the Study;

(ii) Institution shall comply with the applicable provisions of Article 10 concerning the return of any MSD provided materials (if applicable);

(iii) except in the event of termination because of a material breach by Institution or Principal Investigator, and unless otherwise specified in writing between the parties, the total sums payable by MSD pursuant to this Agreement shall be pro-rated for actual work performed in accordance with the Protocol to date of notice of termination including Protocol required non-cancelable commitments marked as such in the budget for the Study, with any unearned portion of funds previously provided by MSD under the terms of this Agreement being refunded to MSD;

(iv) in the event of termination as a result of a material breach by Institution or Principal Investigator, the parties agree to make a good faith effort to reach agreement to compensate Institution for actual work performed in accordance with the Protocol to date of notice of termination with any unearned portion of funds previously paid by MSD to Institution being refunded to MSD; and

(v) Institution and Principal Investigator shall return to MSD at MSD's request all Confidential Information (as defined in Article 8 hereof) owned or controlled by MSD and in the possession of Institution or Principal Investigator.

D. The termination or expiration of this Agreement shall not relieve either party of its obligation to the other in respect of:

(i) retaining in confidence all Confidential Information (as defined in Article 8 hereof);

(ii) complying with record keeping and reporting obligations (under Article 6 hereof);

(iii) complying with any publication obligations (under Article 9 hereof) and obtaining any written approval and consents for any publicity and promotional purposes (under Article 15 hereof);

(iv) compensation for services performed to date of notice of termination, except as set forth in Article 5.C (iv) hereof;

(v) complying with obligations relating to any MSD provided material, if applicable (under Article 10 hereof); and

(vi) obligation to assign Inventions and assist in obtaining patent protection (under Article 11 hereof)

all of which obligations are binding on the appropriate party and shall remain in full force and effect as set forth in this Agreement.

6. **Records and Reports**

A. Principal Investigator and Institution shall have the following record keeping and reporting obligations:

(i) preparation and maintenance of written records in accordance with laws, regulations and good clinical practice;

(ii) preparation and submission of Study status reports via the MISP database every three (3) months or, if the parties can agree to an alternative format, such format as the parties have otherwise mutually agreed upon in writing (failure

to provide Study status reports may result in immediate termination of this Agreement); and

(iii) a Study manuscript for a peer reviewed journal or final study report according to mutually agreed upon content within one-year from the final subject being examined or receiving an intervention for the purposes of final collection of data of the Study regardless of the Study results. The final study report shall be made of descriptive data, tables, and data listings, and contain all relevant adverse experiences as a line listing or table. Any Study subject level data submitted to MSD will only be coded with a number and no other personal identifiers such as birth date or Study subject initials.

B. Safety Reporting and Related Procedures

(i) For purposes of this Agreement the below terms shall be defined as follows:

"**Adverse Event**" or "**AE**" shall mean any untoward medical occurrence in a Study subject who is administered a pharmaceutical product regardless of whether or not a causal relationship with the product exists. By way of example and without limitation, an AE can be any unfavorable and unintended sign (for example, an abnormal laboratory finding), symptom, or disease temporally associated with the use of the medicinal drug.

"**Serious Adverse Event**" or "**SAE**" shall mean any AE which is fatal or life threatening, results in persistent or significant disability/incapacity, requires inpatient hospitalization, prolongation of existing inpatient hospitalization, or is a congenital anomaly/birth defect, is another important medical event. Other important medical events that may not result in death, may not be life-threatening, or may not require hospitalization may be considered a Serious Adverse Event when, based upon appropriate medical judgment, they may jeopardize the patient or subject and may require medical or surgical intervention to prevent one of the other outcomes listed previously. Examples of such medical events include allergic bronchospasm requiring intensive treatment in an emergency room or at home and blood dyscrasias or convulsions that do not result in inpatient hospitalization.

"**Non-Serious Adverse Event**" or "**NSAE**" shall mean any Adverse Event that does not meet the criteria of an SAE.

"**Special Situations**" shall include the following:

- Overdose
- Exposure to product during pregnancy or lactation
- Lack of therapeutic effect
- Off-label use, medication error, misuse, abuse, or occupational exposure
- Suspected transmission via a medicinal product of an infectious agent
- Unexpected Therapeutic Benefit/Effect

"Product Quality Complaint (PQC)" shall include any communication that describes a potential defect related to the identity, strength, quality, purity or performance of a product

identified by an external customer. This includes potential device or device component malfunctions.

"Malfunction" shall mean the failure of a device (including the device component of a combination product) to meet its performance specifications or otherwise perform as intended. Performance specifications include all claims made in the labeling for the device.

(ii) Adverse Event and Product Quality Complaint Reporting. The Study is a non-interventional study. No individual administration of any therapeutic or prophylactic agent is required under the Protocol. Therefore, the Institution and Principal Investigator are not obligated to solicit SAEs, NSAEs, Special Situations or PQCs. However, if the Principal Investigator happens to become aware of an SAE (regardless of causality), a NSAE which is felt to be causally related to any MSD product, a Special Situation (regardless of seriousness or causality) or PQC, during or following the use of a MSD product, then the event/PQC shall be forwarded to MSD Argentina. Notification to MSD Argentina shall be in the form of a completed MSD AE/PQC form, CIOMS I/MedWatch (or other mutually agreed upon format) within one (1) business day from receipt for a PQC, a SAE or Special Situation and ten (10) calendar days from receipt of a NSAE. This information shall be transmitted to MSD Argentina by email to aquimsd.argentina@merck.com or such other contact information as provided by MSD in writing. MSD will confirm receipt of the report within one (1) business day. If confirmation is not received within one (1) business day, Principal Investigator/Institution will contact MSD to determine if the original report needs to be re-sent. Principal Investigator/Institution will maintain a record of the confirmation. All information shall be transmitted in the English language and contain the reporter's name and the Study subject identifier code, if available. Events for non-MSD products shall be handled according to the institution's policy or local laws and regulations. As applicable, Institution and Principal Investigator shall fully comply with all of their respective reporting obligations to the applicable regulatory authorities with respect to any AE, SAE or PQC that arises from the Study.

7. **Funding**

MSD shall provide limited funding in support of the Study. The budget for the Study is set forth in Exhibit A and the payment schedule is set forth in Exhibit B. Institution shall send to MSD an invoice or documentation sufficient for MSD to determine a payment is due according to the schedule set forth in Exhibit B. Final payment shall be made upon receipt of a manuscript quality final report to MSD. The payments from MSD for the services provided by Institution and Principal Investigator hereunder (i) represent the fair market value for such services and do not exceed fair market value for the actual Study cost, (ii) were negotiated in an arm's length transaction, and (iii) have not been determined in a manner that takes into account the volume or value of any referrals or business otherwise generated between the parties. For work performed or expenses incurred that MSD is obligated to make payment on, Institution and Principal Investigator will not seek additional reimbursement from another source.

8. **Confidential Information**

A. During and for a period of ten (10) years after the expiration or early termination of this Agreement, Institution and Principal Investigator shall retain in confidence all test articles and proprietary data and/or information obtained from MSD including, but not limited to, the

investigator's brochure if provided, and any other information or material disclosed under confidential disclosure agreements previously entered into between the parties ("Confidential Information"). This restriction shall not apply to Confidential Information that:

(i) is or becomes public knowledge (through no fault of Institution or Principal Investigator); or

(ii) is lawfully made available to Institution or Principal Investigator by an independent third party owing no obligation of confidentiality to MSD with regard thereto (and such lawful right can be properly demonstrated by Institution or Principal Investigator); or

(iii) is already in Institution's or Principal Investigator's possession at the time of receipt from MSD (and such prior possession can be properly demonstrated by Institution or Principal Investigator); or

(iv) is published in accordance with the express terms of this Agreement.

B. Institution may disclose Confidential Information to the extent it is required by law, regulation, rule, act or order of any governmental authority or agency. To permit MSD an opportunity to intervene by seeking a protective order or other similar order, in order to limit or prevent disclosures of Confidential Information, Institution or Principal Investigator shall immediately notify MSD, in writing, if it is requested by a court order or a governmental authority or agency to disclose Confidential Information in Institution's or Principal Investigator's possession and thereafter Institution or Principal Investigator shall disclose only the minimum Confidential Information required to be disclosed in order to comply, whether or not a protective order or other similar order is obtained by MSD.

C. Subject to applicable legal and regulatory requirements, Institution and Principal Investigator agree to promptly return to MSD, upon its request, all Confidential Information obtained from MSD or belonging to MSD pursuant to this Agreement; provided, however, that Institution's legal counsel may retain one copy of Confidential Information in a secure location for purposes of identifying Institution's obligations under these confidentiality provisions.

D. Institution and Principal Investigator shall limit disclosure of Confidential Information received hereunder to only those of its Study Staff who are bound by a written agreement with terms equivalent to or more stringent than this Agreement and who are directly involved with the Study and only on a need to know basis. Institution and Principal Investigator shall advise its Study Staff upon disclosure to them of any Confidential Information of the proprietary nature thereof and the terms and conditions of this Agreement and shall use all reasonable safeguards to prevent unauthorized use or disclosure by such Study Staff. Institution and Principal Investigator shall be responsible for any breach of these confidentiality provisions by its Study Staff.

E. Institution and Principal Investigator acknowledge and expressly agree that any disclosure of Confidential Information in violation of this Agreement would be detrimental to MSD's business and cause it irreparable harm and damage. In accordance with applicable law and in addition to any

other rights and remedies provided herein, MSD shall be entitled to seek equitable relief by way of injunction or otherwise.

F. Institution shall neither disclose to MSD nor induce MSD to use any secret or confidential information or material belonging to others, including other sponsors of other clinical trials.

9. **Data, Publications and Other Rights**

In recognition of the importance of disseminating information relating to any novel or important observations or results arising from the Study and understanding that such need must be balanced with MSD's obligations to maintain control over Confidential Information as well as to comply with appropriate rules and regulations, the parties hereby agree to the following:

A. All Study data and results will be owned by Institution. Institution agrees that all Study data and results generated during the course of the Study may be used fully by MSD for any legitimate business purpose without any additional payments being made to Institution or Principal Investigator. Institution agrees not to provide any commercial third party with access to or with the right to use the data or results for any purpose without the written permission of MSD which shall not be unreasonably withheld.

B. Subject to the terms and conditions of this Agreement, Institution and Principal Investigator have the right to publish or publicly present the results of the Study. MSD shall have the right to review and comment on any Public Presentation. Principal Investigator and Institution further agree to provide forty-five (45) days written notice to MSD prior to submission for publication or presentation to permit MSD to review drafts of abstracts and manuscripts for publication (including, without limitation, slides and texts of oral or other public presentations and texts of any transmission through any electronic media, e.g. any computer access system such as the Internet, World Wide Web etc., collectively or individually a "Public Presentation") which report any results arising out of the Study. Such forty-five (45) day notice period shall not commence until MSD has received all the relevant data associated with the Public Presentation in order for MSD to properly review and comment on the Public Presentation.

C. No Public Presentation shall contain any Confidential Information of MSD (as defined in Article 8) which for the purposes of this Article 9 shall be deemed to not include the results of the Study or data generated pursuant to the Study. If the parties disagree concerning the accuracy and appropriateness of the data analysis and presentation, and/or confidentiality of MSD's Confidential Information, Institution and/or Principal Investigator agree to meet with MSD's representatives at the clinical Study site or as otherwise agreed, prior to submission of a Public Presentation, for the purpose of making good faith efforts to discuss and resolve any such issues or disagreement. Principal Investigator agrees to acknowledge MSD in any Public Presentation using the following language: "Supported in part by a research grant from Investigator-Initiated Studies Program of Merck Sharp & Dohme LLC. The opinions expressed in this paper are those of the authors and do not necessarily represent those of Merck Sharp & Dohme LLC".

D. If MSD believes there is patentable subject matter contained in any Public Presentation submitted for review, MSD shall promptly identify such subject matter to Institution. If MSD requests and at MSD's expense, Institution and Principal Investigator shall use their best efforts to assist MSD

to file a patent application covering such subject matter with the United States Patent and Trademark Office or through the Patent Cooperation Treaty prior to any publication. MSD shall have the right to delay publication or presentation of any Public Presentation for a period not to exceed ninety (90) days after the initial review period if publication or presentation of such Public Presentation would affect MSD's ability to obtain patent protection for any invention.

E. In making a Public Presentation, Institution and/or Principal Investigator shall comply with all laws, regulations and accepted guidelines of peer reviewed medical journals and any specific guidelines established by congresses and/or the journals to which the Public Presentation will be submitted. Institution and/or Principal Investigator represent that designated authors and contributors on all such Public Presentations shall meet the minimum requirements of International Committee of Medical Journal Editors.

F. Principal Investigator and/or Institution shall be the responsible party as defined in Section 801 of the Food and Drug Administration Amendments Act of 2007 ("Responsible Party").

10. **Clinical Supplies**

The parties agree that MSD is not providing any Study Drug or other drug for use in this Study. If any other clinical supplies are provided by MSD for use in this Study, such supplies may not be used for any other purpose than that stated in the Protocol and may not be transferred to any third party without MSD's approval. All unused materials will be returned to MSD or MSD's representative by Institution at the conclusion of the Study, or upon earlier termination of this Agreement, unless written authorization to destroy or retain them is given by MSD.

11. **Inventions and Patents**

A. This Agreement shall not be deemed or construed to convey, transfer, or license any of such intellectual property rights to Institution, other than the limited rights necessary to permit Institution to conduct the Study during the term of this Agreement. Nothing contained in this Agreement shall be deemed to grant either directly or by implication, estoppel or otherwise any license under any patents, patent applications or other proprietary interests to any other inventions or discoveries of either party.

B. Ownership and rights to any new and patentable or unpatentable discovery, technology, know-how or other intellectual property conceived and/or reduced to practice from the performance of the Protocol and Study (hereinafter "Inventions") shall be governed by the following provisions: Inventions made solely by the Principal Investigator or employees of Institution shall be the property of Institution (hereinafter "Institution Inventions"); and Inventions made jointly by employees or agents of MSD and either the Principal Investigator or employees of Institution shall be the joint property of MSD and Institution (hereinafter "Joint Inventions") with each having the right to exploit and grant licenses without consent of and accounting to the other. Institution will promptly notify MSD in writing of any such Inventions. Institution and MSD shall consult and agree upon the patent filing and prosecution strategy for all Joint Inventions.

C. Institution hereby grants MSD a paid-up non-exclusive royalty free, sub-licensable, worldwide license to all Institution Inventions for any legitimate business purpose, and an exclusive

option to obtain an exclusive, worldwide license for any legitimate business purpose, including the right to grant sub-licenses, to all Institution Inventions and to Institution's entire right, title and interest in and to all Joint Inventions. The parties agree to use good faith efforts to negotiate commercially reasonable terms for any exclusive license. MSD shall execute its option within six (6) months of MSD's receipt of written notice of said invention. In the event that MSD fails to so notify Institution or elects not to obtain an exclusive license, then MSD's option shall expire with respect to said Invention. If the parties fail to reach agreement on the terms for an exclusive license for a particular Invention, then for a period of one (1) year thereafter Institution shall not offer to license the Invention to any third party on materially better terms than those last offered to MSD without first offering such terms to MSD, in which case MSD shall have a period of thirty (30) days in which to accept or reject the offer.

12. **Notice**

Whenever any notice is to be given hereunder, it shall be in writing and mailed postage prepaid by certified or registered mail (return receipt requested), commercial overnight carrier (return receipt requested) or personally delivered to the appropriate party at the address indicated below, or at such other place or places as either party may designate in a written notice to the other. Notice shall be deemed to have been received upon receipt.

To Institution:
Manuel Perez Foundation
Av. Gral. Flores 2125
Montevideo Department, Montevideo 11800
Uruguay
Attn.: Dr. Elizabeth Assandri

To MSD:
MSD Innovation Centre
2 Pancras Square
London, N1C 4AG
United Kingdom
Attn.: E. David G. McIntosh, MBBS, PhD, MPH

13. **Assignment**

The rights and obligations of Institution and Principal Investigator under this Agreement may not be assigned or subcontracted to others without MSD's prior written consent and any attempted assignment or delegation in violation hereof shall be void. Institution and Principal Investigator shall ensure that all third parties who provide services on behalf of Institution or Principal Investigator comply with the terms and conditions of this Agreement. MSD may assign this Agreement to an affiliated company without the prior consent of Institution or Principal Investigator. Notwithstanding any such assignment by MSD, MSD shall remain liable for all of its obligations under this Agreement.

14. **Applicable Law**

This Agreement shall be construed in accordance with the applicable law in the country where Institution and Principal Investigator will perform the Study.

15. **Publicity**

No party shall use the name of another party (or the name of any division or affiliated companies of a party) for promotional purposes without the prior written consent of the party whose name is proposed to be used. Except for Public Presentations under Article 9, no news release, publicity or other public announcement, either written or oral, regarding this Agreement or performance hereunder or results arising from the Study, shall be made by Institution or Principal Investigator without the prior written approval of MSD.

16. **Independent Contractor**

It is agreed by the parties that Institution and Principal Investigator are acting in the capacity of independent contractors hereunder and not as employees, agents or joint venturers of or with MSD. Neither Institution nor Principal Investigator shall have any authority to represent, bind or act on behalf of MSD.

17. **Agreement Modifications**

Neither this Agreement nor the Protocol may be altered, amended or modified except by written document signed by the parties.

18. **Severability**

If any term or condition of this Agreement, the deletion of which would not adversely affect the receipt of any material benefit by a party hereunder, shall be held illegal, invalid or unenforceable, the remaining terms and conditions of this Agreement shall not be affected thereby and such terms and conditions shall be valid and enforceable to the fullest extent permitted by law.

19. **No Waiver**

Failure on the part of a party to exercise or enforce any right conferred upon it hereunder shall not be deemed to be a waiver of any such right nor operate to bar the exercise or enforcement thereof at any time or times thereafter.

20. **Combating Bribery of Public Officials**

Institution and Principal Investigator agree that they will not make any payment, either directly or indirectly, of money or other assets (collectively "Payment") to any Government Official (as defined below) if such Payment is for the purpose of influencing decisions or actions with respect to the subject matter of this Agreement or any other aspect of MSD's business. "Government Official" means (i) any officer or employee of a government, or of a public international organization, (ii) any person acting in an official capacity for or on behalf of any such government or public international organization, and (iii) any official of a political party or candidate for political office. Institution will report any violation of the requirements of this Article to MSD immediately and agrees to make all relevant records and other documentation relating to a violation available for MSD and its representatives review.

21. **Privacy**

A. MSD uses global electronic systems for processing certain information in connection with Investigator Initiated Clinical Trial Research. These systems may include certain Personal Data provided to MSD by Institution and Principal Investigator that relates to persons who participate in or perform work in connection with the conduct of the Study. "Personal Data" means any data relating to an identified or identifiable individual, including data that identifies an individual or that could be used to identify, locate, track, or contact an individual. Personal Data includes both directly identifiable information such as a name, identification number or unique job title, and indirectly identifiable information such as date of birth, unique mobile or wearable device identifier, telephone number, key-coded data and online identifiers such as IP addresses, and includes any data that constitutes "Personal Data" under the GDPR. "Institution Personal Data" is Personal Data provided by Institution, Primary Investigator, and any persons who participate in or perform work in connection with the conduct of the Study to MSD. These parties are individually and collectively called "Institution" for the purposes of this Article 21, but each may exercise their rights described under this Article individually or as a group. The Institution Personal Data used in such systems and for the administration of this agreement generally includes information such as name, specialization, and contact information.

B. Both Institution and MSD shall comply with all applicable data protection laws, including the General Data Protection Regulation (2016/679; the "GDPR").

C. MSD shall ensure that Institution Personal Data is kept accurate and up to date. Institution may request changes to Institution Personal Data by contacting MSD at e-mail address msd_privacy_office@msd.com. Institution may at any time forward to MSD data subject right requests from study subjects and site staff regarding the following rights in relation to Institution Personal Data that MSD Processes:

(i) Right to access and rectification: Institution also has the right to request that inaccurate or incomplete Institution Personal Data be corrected.

(ii) Right to object: including, for example, processing of Institution Personal Data for marketing purposes or when MSD otherwise bases processing of Institution Personal Data on a legitimate interest.

(iii) Right to erasure: requests that Institution Personal Data be erased if e.g. the Institution Personal Data is no longer necessary for the purposes for which it was collected, the processing is unlawful, or the personal data has to be erased to enable MSD to comply with a legal requirement.

(iv) Note that there may be situations where MSD's confidentiality and other obligations under applicable legislation (including Good Clinical Practices) may prohibit MSD from disclosing or deleting Institution Personal Data or otherwise prevent Institution or study subjects from exercising its rights. Except where prohibited by the GDPR or national data protection law, MSD may deny Institution's or study subjects' choice where a particular request would impede MSD in its ability to: (1) comply with a law or an ethical obligation including where MSD is required to disclose personal

information in response to lawful requests by public authorities, including to meet national security or law enforcement requirements, (2) investigate, make or defend legal claims, and (3) perform contracts, administer relationships, or engage in other permitted business activities that are consistent with transparency and purpose limitation principles and were entered into in reliance on the information about people in question. Within fifteen business days of any decision to deny a choice request in accordance with this Article, MSD will document and communicate such a decision to Institution.

D. If Institution directly or on behalf of a study subject has any complaints about how MSD processes Institution Personal Data, or would like further information, please contact MSD at any time. If Institution wishes to file a complaint with a national supervisory authority regarding MSD's processing of Institution Personal Data, contact the affected individual's local data protection authority ("local" meaning where he or she lives or works, or where an alleged data breach has occurred).

E. MSD collects and processes information about Institution when Institution performs a service on MSD's behalf (such as conducting clinical trials), in order to perform the contract MSD has entered into with Institution. MSD may also disclose personal information relating to Institution (including details of any payments made to Institution) as required by regulatory agencies or otherwise as expressly permitted or required under applicable laws. MSD will only process Institution Personal Data for the purposes for which it was collected and as set out above, and Institution Personal Data will only be available to authorized employees holding a position that requires them to process Institution Personal Data to perform their work. Institution Personal Data is processed for no longer than is necessary for the particular purpose. MSD fully complies with its statutory retention obligations and internal retention time policies. MSD has taken appropriate technical and organizational measures to keep Institution Personal Data secure to ensure that only authorized persons are given access to Institution Personal Data. MSD also has internal policies in place for secure processing of Personal Data.

F. MSD will not disclose Institution Personal Data to any third parties unless required to do so under applicable laws or to perform the contract MSD has entered into with Institution. However, Institution Personal Data may be transferred to and processed by third-party providers which perform services for MSD ("data processors") to enable these companies to perform the services requested by MSD. Only Institution Personal Data that is necessary to fulfill the purposes stated above, will be provided to these companies. All third-party providers must follow MSD's instructions and applicable written data processor agreements and any other agreements that are in place between MSD and third-party providers and must implement appropriate technical and organizational measures for the protection of Institution Personal Data.

G. MSD processes Personal Data, which may include Institution Personal Data, on servers in the EU. In addition, MSD processes Personal Data in the United States, and as such MSD may transfer Institution Personal Data to a location outside of the EU pursuant to the GDPR or other applicable national law, including applicable Standard Contractual Clauses. The level of information protection in countries outside the EU may be lower than that offered within the EU. Where this is the case, MSD will implement appropriate measures under the GDPR or other applicable national law to ensure that Institution Personal Data remains protected and secure. The

European Commission has recognized the United States as providing an adequate level of data protection following the Commission Implementing Decision (EU) of 10 July 2023 pursuant to Regulation (EU) 2016/679 of the European Parliament and of the Council on the adequate level of protection of personal data under the EU-US Data Privacy Framework, it being understood that the scope of this adequacy decision is limited to commercial organizations participating in the EU-US Data Privacy Framework. MSD is an actively certified organization under the Data Privacy Framework. In addition, MSD has entered into Binding Corporate Rules which have been approved by the European Union.

H. MSD is the controller of Institution Personal Data for the purposes described above. The contact details of MSD's offices can be found at www.msd.com . For questions regarding MSD's processing of personal data, please feel free to contact MSD's data protection team at: msd_privacy_office@msd.com.

22. **Force Majeure**

Noncompliance by a party with the obligations of this Agreement due to force majeure, (laws or regulations of any government, war, civil commotion, destruction of production facilities and materials, fire, flood, earthquake or storm, labor disturbances, shortage of materials, failure of public utilities or common carriers), or any other causes beyond the reasonable control of the applicable party, shall not constitute breach of this Agreement and such party shall be excused from performance hereunder to the extent and for the duration of such prevention, provided it first notifies the other party(ies) in writing of such prevention and that it uses its best efforts to cause the event of the force majeure to terminate, be cured or otherwise ended.

23. **Entire Understanding**

This Agreement, including any exhibits and schedules hereto, constitutes the entire agreement between the parties with respect to the subject matter hereof. This Agreement supersedes and cancels all previous agreements among the parties, written and oral in respect of the subject matter hereof. In the event of any inconsistency between this Agreement and the Protocol, the terms of this Agreement shall govern.

Signatures follow on next page.

IN WITNESS WHEREOF, the parties have caused this Agreement to be executed, by duly authorized representatives, as of the last date written below.

MANUEL PEREZ FOUNDATION

BY _____

NAME Decan Prof. Dr. Arturo Briva

TITLE President

DATE _____

MERCK SHARP & DOHME LLC

BY _____

NAME Pamela M. Polino

TITLE Associate Vice President,
Global Medical and Scientific Affairs,
Merck Research Laboratories

DATE _____

MANUEL PEREZ FOUNDATION

BY _____

NAME Gabriela Gonzalez

TITLE Executive Secretary

DATE 22/05/24

GLOBAL AGREEMENTS
Christina L. McAnally

29 April 2024

I hereby acknowledge that I have read and agree with the terms of this Agreement, including the Protocol, and that I will act and perform my duties in the Study in accordance therewith. I hereby also confirm that I agree to the processing, transfer and export of my personal data for use and disclosure as needed for purposes related to the performance of this Agreement and any related health authority or regulatory inspection or request.

_____

Dr. Elizabeth Assandri
Principal Investigator

DATE 22/05/24

EXHIBIT B
(Payment Schedule)

Total Number of Patients	70
Total budget amount (in local currency)	UYU 4,549,603.31

The Grant shall be due and payable in local currency as follows for IIS#_101798_:

Payment 1: UYU 1,364,880.99 (or 30% of the total Grant) upon complete execution of this Agreement, receipt of Institutional Review Board approval.

Payment 2: UYU 1,137,400.83 (or _25_ % of the total Grant) upon receipt of satisfactorily completed quarterly Status Update indicating the _50_% milestone has been achieved. Paid based on actual enrollment of evaluable subjects _1_ through _35_

Payment 3: UYU 1,137,400.83 (or _25_ % of the total Grant) upon receipt of satisfactorily completed quarterly Status Update indicating the _100_% enrollment milestone has been achieved. Paid based on actual enrollment of evaluable subjects _36_ through _70_

Final Payment: UYU 909,920.66 (20% of the total Grant) upon receipt of a manuscript quality final report to MSD. (MSD committee review required prior to final payment release)

Upon receipt of paperwork satisfactorily evidencing that the amount is due and payable as reasonably determined by MSD, a check for the applicable amount will be issued within 90 days.

MSD reserves the right to prorate payments based on work performed at any time.

EXHIBIT A
(Budget)

TRIAL INFORMATION	[illegible]
Investigator Name:	Elizabeth Assandri
Length of Trial (Months):	36
Phase (I-IV):	IV
Indication/ICD Code:	A48.8
Protocol Title:	Observational, descriptive, prospective, longitudinal study of the characteristics, outcome, and follow-up after hospital discharge of children with pneumonia complicated by pleuropulmonary suppuration and/or pulmonary necrosis.
Country:	URUGUAY
Number of Sites:	1
Number of Charts/Patients:	70
Overhead Percentage:	7.00%
Local Currency:	UYU
Exchange Rate:	0.026
Exchange Rate Date:	

Totals	UYU	USD
Total Cost Per Patient (incl. OH):	56,594.33	1,471.45
Total Cost Per Site:	0.00	0.00
Total Cost For All Patients (incl. OH):	3,961,603.31	103,001.69
Total Cost for All Sites:	0.00	0.00
Total Study Costs:	588,000.00	15,288.00
Grand Total Study Cost:	4,549,603.31	118,289.69

Hourly Rate Calculator	
Annual Salary:	
Hourly Rate:	0.00

Per Patient Costs By Activity Type (Overhead Applied)

Per PATIENT Fees: Visit Activities	Quantity Per Patient	Unit Cost in UYU	Unit Cost in USD	Total Cost in UYU	Total Cost in USD	Comments
*ADVE | Adverse Events Assessment			0.00	0.00	0.00	
*INEX | Inclusion/Exclusion Criteria			0.00	0.00	0.00	
*INCO | Informed Consent Process			0.00	0.00	0.00	
RCM | Review Concomitant Medications			0.00	0.00	0.00	
			Total Per PATIENT Fees: Visit Activities	0.00	0.00	

Per PATIENT Fees: Administrative Fees Note: Costs will be multiplied by the number of patients. One-time costs should be listed under Per Study costs.	Quantity per Patient	Unit Cost in UYU	Unit Cost in USD	Total Cost in UYU	Total Cost in USD	Comments
#1118 | Patient Reimbursement Per Patient (Total Reimbursement)	2	385.70	10.03	771.40	20.06	patients public transportation
#1110 | Physician's Fees without Exam Costs (Per Patient)			0.00	0.00	0.00	
#1113 | Fees: Coord, Nurse, Admin, Tech (Per Patient)			0.00	0.00	0.00	
			Total Per PATIENT Fees: Administrative Fees	771.40	20.06	

Per PATIENT Fees: HOURLY Fees Note: Costs will be multiplied by the number of patients. One-time costs should be listed under Per Study costs.	Hours per Patient	Unit Cost in UYU	Unit Cost in USD	Total Cost in UYU	Total Cost in USD	Comments
V1134 | Hourly Rate: Investigator, Doctor, Physician	53.5	350.00	9.10	18,725.00	486.85	[illegible]
V1132 | Hourly Rate: Study Coordinator, CRA, Monitor Visits, CRF Review	26.7	550.00	14.30	14,685.00	381.81	Supervisor will conduct the study during the 3 year, w
V1135 | Hourly Rate: Nurse			0.00	0.00	0.00	
V1131 | Hourly Rate: Data Entry, Keypunch			0.00	0.00	0.00	
V1136 | Hourly Rate: Dietician			0.00	0.00	0.00	
V1137 | Hourly Rate: Laboratory Technician	4.45	530.00	13.78	2,358.50	61.32	
V1142 | Hourly Rate: Statistician, Data Manager	2.22	350.00	9.10	777.00	20.20	
V1140 | Hourly Rate: Secretary, Administrative Support, Clerical			0.00	0.00	0.00	
V1145-V1161 | Hourly Rate: Specialist (Options: Cardiology, Dermatology, Gastroenterology, OB/GYN, Ophthalmology, Oncology, Rheumatology, Pediatrics, Neurology, Psychiatry, Orthopedics, Endocrinology, Hematology, Pulmonology, Geriatrics, Immunology, Urology)	44.5	350.00	9.10	15,575.00	404.95	team: 2 surgeons 2 pneumologists 1 microbiologist (all make the same hourly rate)
			Total Per PATIENT Fees: HOURLY Fees	52,120.50	1,355.13	

Note: If any costs do not fit into one of the sections under Per Patient Costs, they should be added to the section for Additional Costs at the bottom of this sheet with the cost type "Patient" selected.

OTHER DIRECT COSTS - BY SITE OR STUDY (NO OVERHEAD APPLIED)

Per SITE Costs: Administrative & Study Conduct Note: Costs will be multiplied by the number of sites. For one-time costs use the Study costs below.	Quantity Per Site	Unit Cost in UYU	Unit Cost in USD	Total Cost in UYU	Total Cost in USD	Comments
*ADMN | Administrative Fees: Costs			0.00	0.00	0.00	
*AR01 | Archiving/Document Storage Fixed Fee			0.00	0.00	0.00	
*CHAR | Chart Review Fee, Site (One Fee for all reviews for the site)			0.00	0.00	0.00	
*CHARC | Chart Review Fee, Per Chart (Fee per Chart/Patient reviewed at site)			0.00	0.00	0.00	[illegible]
#1124 | Site Start-up Costs			0.00	0.00	0.00	
#0001 | EC/IRB Fee			0.00	0.00	0.00	
*IRBF | IRB Preparation Fee			0.00	0.00	0.00	
*IRBR | IRB Renewal Fee			0.00	0.00	0.00	
*IRBA | IRB Amendment Fee			0.00	0.00	0.00	
*IRBV | IRB Review Fee			0.00	0.00	0.00	
*PRAD | Protocol Amendment Fee			0.00	0.00	0.00	
#1114 | Advertising (Site)			0.00	0.00	0.00	
*STRN | Institution Site Training			0.00	0.00	0.00	
*SCLO | Study Close-out Fee			0.00	0.00	0.00	
*PAST | Pathology Set up Fee			0.00	0.00	0.00	
*EDCT | EDC Training Fees			0.00	0.00	0.00	
*MONF | Monitoring Fee, Per Site			0.00	0.00	0.00	
			Total Per SITE Costs: Administrative & Study Conduct	0.00	0.00	

Please Note: If any Per SITE costs do not fit into one of the above coded costs, they should be added to the section for Additional Costs at the bottom of this sheet with the cost type "Site" selected.

Per STUDY Costs: Administrative & Study Conduct	Quantity per Study	Unit Cost in UYU	Unit Cost in USD	Total Cost in UYU	Total Cost in USD	Comments
IIT Custom | Database Fees (Incl. Database Design & Licensing Fees)			0.00	0.00	0.00	
IIT Custom | Manuscript Prep			0.00	0.00	0.00	
IIT Custom | Protocol Prep			0.00	0.00	0.00	
IIT | Publication Costs			0.00	0.00	0.00	
			Total Per STUDY Costs: Administrative & Study Conduct	0.00	0.00	

Please Note: If any Per STUDY costs do not fit into one of the above coded costs, they should be added to the section for Additional Costs at the bottom of this sheet with the cost type "Site" selected.

ADDITIONAL COSTS [illegible]

Cost Description	Cost Type	Quantity	Unit Cost in UYU	Unit Cost in USD	Total Cost in UYU	Total Cost in USD	Comments	[illegible]	[illegible]
Respiratory Tx: spirometry, lung volumes, oxycapnography	Study	210	1,800.00	46.80	378,000.00	9,828.00			
Reagents for serotyping by IT PCR Multiplex RT-PCR for identification of pathogens	Study	70	3,000.00	78.00	210,000.00	5,460.00			
(Enter Description Here)				0.00	0.00	0.00			
(Enter Description Here)				0.00	0.00	0.00			
(Enter Description Here)				0.00	0.00	0.00			
(Enter Description Here)				0.00	0.00	0.00			
(Enter Description Here)				0.00	0.00	0.00			
(Enter Description Here)				0.00	0.00	0.00			
(Enter Description Here)				0.00	0.00	0.00			
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(Enter Description Here)				0.00	0.00	0.00			
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(Enter Description Here)				0.00	0.00	0.00			
(Enter Description Here)				0.00	0.00	0.00			
(Enter Description Here)				0.00	0.00	0.00			
(Enter Description Here)				0.00	0.00	0.00			
(Enter Description Here)				0.00	0.00	0.00			
(Enter Description Here)				0.00	0.00	0.00			
(Enter Description Here)				0.00	0.00	0.00			
				Total Additional STUDY Costs	588,000.00	15,288.00			
				Total Additional SITE Costs	0.00	0.00			
				Total Additional PATIENT Costs	0.00	0.00			
				Total Additional [illegible] Costs	0.00	0.00			