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CLINICAL TRIAL AGREEMENT – POISE-3

This **CLINICAL TRIAL AGREEMENT** ("**Agreement**"), effective as of the date of last signature ("**Effective Date**") is made between:

Hamilton Health Sciences Corporation ("**HHSC**"), through its **Population Health Research Institute** ("**PHRI**"), at 237 Barton Street East, Hamilton, Ontario, L8L 2X2, Canada, represented by its Director

-and-

CBCI Society for Medical Education, ("**CBCI**") established and registered under the Karnataka Societies Registration Act, 1980, having its address at St. John's National Academy of Health Sciences, John Nagar, Sarjapur Road, Koramangala, Bangalore-560034, Karnataka, India, represented by its Secretary (hereafter referred as the "**Society**")

-and-

St. John's Research Institute, ("**SJRI**") a unit of the Society, having its address at St. John's National Academy of Health Sciences, John Nagar, Sarjapur Road, Koramangala, Bangalore-560034, Karnataka, India, represented by its Dean (hereafter referred as "**Institute**")

- and-

Division of Clinical Research and Training ("DCRT"), a Division of SJRI, with its administrative office at St. John's Research Institute, St. John's National Academy of Health Sciences, Bangalore-560 034 Karnataka; India, represented by, Dr. Denis Xavier, Vice Dean (PG), Professor, Dept. of Pharmacology, St. John's Medical College and Head DCRT (hereafter called "**National Leader**")

-and-

Sumandeep Vidyapeeth & Dhiraj General Hospital, with its principal place of business at General Surgery Department, AT & PO: Piparia, Waghodia Road, Distt-Vadodara, Gujurat, 391760, India (hereinafter the "**Institution**")

-and-

Dr. Vipul Gurjar, as the principal investigator at the institution, with office at Sumandeep Vidyapeeth & Dhiraj General Hospital, General Surgery Department, AT & PO: Piparia, Waghodia Road, Distt-Vadodara, Gujurat, 391760, India (hereinafter the "**Investigator**")

WHEREAS:

A. PHRI is coordinating and is the sponsor of a multi-centre clinical trial entitled **P**eri**O**perative **I**Schemic **E**valuation-3 (**POISE-3**) ("**Project**"), the protocol including any amendments from time to time ("**Protocol**") is incorporated hereto by reference;

B. PHRI may also conduct substudies in conjunction with the Project ("**Substudy(ies)**"), and in the event that Site participates in any Substudies, all references to the Project shall include Substudy(ies), and the references to the Protocol shall include any protocols related to such Substudy(ies);

Attested CTC

Sumandeep Vidyapeeth Deemed University

St. John's Research Institute Bangalore

C.B.C.I. SOCIETY FOR MEDICAL EDUCATION Secretary BANGALORE-34

30/11/2023

DS

SUMANDEEP VIDYAPEETH

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

C. PHRI has an agreement with SJRI to carry out national coordination activities in India for the Project;

D. DCRT, SJRI will be the National Leader Office ("**NLO**") Dr. Denis Xavier, Vice Dean (PG), Professor Dept. of Pharmacology, St. John's Medical College as its Head;

E. Investigator and Institution possess the resources and expertise to carry out a portion of the Project for a prescribed fee and wish to assist PHRI and NLO by acting as a site for the Project. The Investigators and Institution are hereinafter referred to jointly and severally as the "**Site**" and the activities carried out by the Site for the Project is referred to as the "**Study**";

F. The Study has been approved by the Sumandeep Vidyapeeth Institutional Ethics Committee Ethics Committee (wherein such committee would approve the conducting of a clinical trial) at the Institution;

G. NLO obtained regulatory approval from Health Ministry Screen Committee (HMSC), Indian Council of Medical Research (ICMR) for conduct of a clinical trial in human subjects and has been registered on the Clinical Trials Registry of India (CTRI).

Each party is hereinafter referred to individually as a "**Party**" and collectively as the "**Parties**".

NOW THEREFORE, in consideration of the terms and conditions contained herein, the Parties agree as follows:

ARTICLE 1. PERFORMANCE OF THE STUDY

1.1 **Compliance:** The Parties agree to carry out the Study in conformance with the following: (a) all applicable requirements of any governmental, regulatory or other body that has authority with respect to the performance of the Study ("**Regulatory Authority(ies)**"); (b) generally accepted standards of good clinical practice, including but not limited to, to the extent adopted by the relevant Regulatory Authority, the Guidance for Good Clinical Practice of the International Conference on Harmonization, and all applicable laws, regulations and guidelines governing the conduct of human clinical research in the jurisdiction of the Institution (together with (a) as "**Applicable Laws**"); (c) the Protocol; and (d) this Agreement.

1.2 **Investigator:** The Study shall be carried out under the direction and supervision of the Investigator.

1.3 **Study Personnel:** Site represents that, during the course of the Study, all subinvestigators, employees, contractors, affiliates, agents and any other persons performing services for the Study (together as "**Personnel**") shall have the appropriate training, information, licenses, approvals, and certifications necessary to safely, adequately and lawfully perform the Study in accordance with this Agreement. Further, Site shall be responsible to ensure that the Personnel have read and understood the Protocol and shall perform their activities and fulfill their obligations in a timely and competent manner.

1.4 **Informed Consent Form:** PHRI shall provide Site with a template informed consent form ("**ICF**") for the Study. Site shall, prior to initiation of the Study and during the conduct of the Study, obtain and maintain written approval from its/his/her institutional review board or ethics review board ("**IRB**") for the Study. Any changes to the ICF require the prior written approval of both the IRB, NLO and PHRI.

1.5 **Subjects:** Site shall obtain a completed and signed ICF from each subject participating in the Study ("**Subject**") prior to enrolling the Subject into the Study, and keep the Subjects informed throughout the Study.

1.6 **Recruitment:** Site may commence recruitment of Subjects upon receipt of an authorization to do so from PHRI/NLO. Site will use diligent efforts to recruit Subjects in accordance with the Protocol. The Parties acknowledge that the Project is a multi-centre study and that recruitment is

on a competitive basis. Once the Project recruitment goal has been reached, PHRI reserves the right to notify Site to limit or cease further recruitment, and Site shall immediately comply upon receipt of any such notice.

1.7 **Conflict:** Site represents and warrants that it/he/she is not presently, and shall not be at any time during the performance of the Study under any obligation to a third party or subject to any impediments which would: (a) prevent, inhibit or negatively affect their performance of the Study, (b) create a conflict of interest or (c) otherwise impair the acceptance by a Regulatory Authority of the data or results collected by Site.

1.8 **Debarment:** Site represents that neither it/he/she nor any of the Personnel has been or is under investigation by a Regulatory Authority for debarment, disqualification, or any similar regulatory action, and that it/he/she has no notice or knowledge of debarment, disqualification, or any similar regulatory action by any Regulatory Authority in another jurisdiction. Furthermore, Site shall, during the term of this Agreement and for three (3) years following its expiration or early termination, promptly notify PHRI in the event of such debarment or threat of debarment, conviction, disqualification, or indictment of Site or Personnel.

1.9 **Subject Safety:** PHRI/NLO agrees to notify Site promptly upon receipt of Study information that would directly affect the health or safety of Subjects. Site shall without delay inform all Subjects and the IRB, as applicable. PHRI shall not be liable for the failure of Site to immediately inform Subjects or IRB of such new information. Site shall promptly report all safety data and information, including but not limited to any failure to comply with or deviations from the Protocols, to PHRI/NLO in accordance with the requirements of the Protocol.

1.10 **Records:** Site shall prepare, maintain and store accurate and complete written records and supporting documentation for each Subject ("**Source Documents**") in accordance with the instructions provided by PHRI/NLO and Applicable Laws. Site shall prepare and submit accurate and complete case report forms and all additional documentation ("**CRFs**") for each Subject to PHRI as required by the Protocol. Site shall reasonably cooperate with PHRI/NLO to promptly resolve all data queries from PHRI/NLO and provide such Source Documents as may be required. In accordance with the obligations in **ARTICLE 5 (Privacy)**, Site and the Personnel shall ensure that any data or Source Documents disclosed to PHRI/NLO does not include any information that would personally identify a subject and/or any personal health information ("**PHI**") unless permitted by signed ICFs and/or other authorizations.

1.11 **Audit and Monitoring:** Site shall cooperate with and permit Regulatory Authorities or PHRI/NLO to examine and inspect the facilities and equipment required for performance of the Study and to inspect and copy all data, reports, work products and results relating to the Study. In relation to visits by PHRI/NLO and/or its representative, the Parties will mutually and reasonably agree upon dates and times taking into account the reason for such visit. For clarity, access to records for monitoring or audit does not entitle PHRI/NLO to make or retain a copy of any Subject's personal identification information or PHI, as more particularly specified in **ARTICLE 5 (Privacy)**, unless such copying is permitted in accordance with the ICF or any other authorizations. Site understands that clinical trial monitoring is essential to good clinical practices and agrees to cooperate with PHRI/NLO to enable its monitoring activities without undue restriction. If Site is notified of an inspection by a Regulatory Authority, Site shall forthwith inform PHRI/NLO about the pending inspection and permit PHRI/NLO, or any person designated by PHRI/NLO, to attend the inspection unless prohibited by Applicable Laws or court order. Site shall forthwith communicate the information that arises from such inspections to PHRI/NLO, unless prohibited by Applicable Laws or court order. The Parties agree that any consideration payable for the assistance of Site for any audits and inspections is included in the consideration payable hereunder, whether or not itemized as such.

1.12 **Change of Investigator:** Should Investigator leave the Institution or otherwise become unavailable during the term of this Agreement, PHRI/NLO shall cooperate with Institution to find a replacement investigator who is acceptable to both Institution and PHRI/NLO. Institution shall require the replacement investigator to agree to comply with and be bound by all the terms and conditions hereof. Notwithstanding this, PHRI/NLO may elect not to approve any person

proposed as a replacement investigator, in which event PHRI/NLO shall have the right to terminate this Agreement in accordance with **ARTICLE 10 (Termination)**.

1.13 **Study Product:** Site shall obtain the drug product required for use in the Study ("**Product**") from its local pharmacy, the cost of which is included in the Payment Schedule attached herein as **Exhibit 1**. Investigator shall: (a) use the Product solely for the purposes of conducting the Study, and (b) ensure the Product is stored in accordance with all instructions provided by the local pharmacy and the Product labels. Site shall control and/or limit access to the Product to the Personnel, and provide up-to-date records showing receipt and dispensing of the Product in accordance the Protocol and Applicable Laws.

ARTICLE 2. TERM

2.1 This Agreement shall commence on the Effective Date specified above, and continue until 31st December 2022, unless otherwise terminated earlier in accordance with **ARTICLE 10 (Termination)** ("**Term**").

ARTICLE 3. COMPENSATION AND PAYMENT

3.1 In consideration for the work performed pursuant to this Agreement, PHRI agrees to pay Site in accordance with the Payment Schedule attached herein as **Exhibit 1** and Payment Rule Form attached as **Exhibit 2**.

3.2 Site shall review the details accompanying each payment and inform PHRI in writing of any discrepancies between the payment received and the payment expected. Site shall inform PHRI of any final discrepancies no later than four (4) months after the Project database is locked. Should PHRI not receive written notice of any final discrepancies within such four (4) month period, all payments required to be made hereunder shall be deemed to have been made in full.

3.3 Site represents and warrants that it/he/she is not a resident or citizen of Canada for tax purposes.

ARTICLE 4. CONFIDENTIAL INFORMATION

4.1 Site agrees to maintain or cause to be maintained in confidence all information received, resulting from and related to the Project, including but not limited to, the Protocol and CRFs ("**Confidential Information**"). This obligation shall be binding for a period of ten (10) years from the termination or completion of the Project. Site will not disclose the Confidential Information without the prior written approval of PHRI/NLO. Site may disclose Confidential Information to Personnel and the IRB to the extent required for the proper conduct of the Study, provided that each person to whom disclosure is made is fully informed of the confidential nature of the information and agrees to keep it confidential in accordance with this Agreement.

4.2 The obligations in **Section 4.1** will not apply to Confidential Information if and to the extent only that it: (a) is or later becomes known to the public or is in the public domain, other than by an act or omission of Site; (b) is previously known to Site, before the Effective Date or prior to Site having signed a confidentiality agreement with PHRI in connection with the Project, as evidenced by written records; (c) is lawfully obtained from a third party and such third party has a legal right to disclose the information; or (d) is independently developed by Site without the use of the Confidential Information, as evidenced by written records.

ARTICLE 5. PRIVACY

5.1 All Parties shall comply with Applicable Laws regarding the Confidential Information, including but not limited to protected or personal information, PHI and all data received or obtained in the course of the Project. Access to PHI and/or personal information shall be provided only to the extent permitted by the Subject's ICF or other authorization and Applicable Laws. Site shall de-identify all information, data and documents prior to providing access to PHRI/NLO, however in the event PHRI/NLO receives or otherwise has access to a Subject's PHI and/or personal

information PHRI/NLO shall hold the PHI and/or personal information in confidence in accordance with all Applicable Laws, the signed ICF or other authorization.

ARTICLE 6. INTELLECTUAL PROPERTY

6.1 PHRI shall own and have all rights, title and interest in: (a) all Project information, documents and data collected; (b) results derived from the performance of the Project in all forms and formats, and (c) any discovery or invention that may arise in the course of the Project by Site or the Personnel. Notwithstanding this, Site may use the data and results of the Study for its/his/her internal non-commercial research and educational purposes provided that until the Project results are public, as provided in **ARTICLE 7 (Publication)**, Site shall not make the results of the Study available to third parties without the prior written consent of PHRI. Subject medical charts shall remain the property of Site.

6.2 Site disclaims all rights, title and interest to the data and results, to any and all intellectual property arising out of or in connection with the Project, and to information and documents received by Site as a result of or in the course of performing the Study, except to the extent that such rights are expressly granted hereunder. Any discovery or invention shall be promptly communicated to PHRI. PHRI shall file and prosecute any patent applications, at its expense and in its sole discretion. Site and the Personnel agree to provide reasonable assistance with any patent applications. Any compensation payable for the assignment of the inventor rights is included in the consideration payable hereunder, whether or not itemized as such. Institution shall be responsible for payments to Investigator or Personnel according to Applicable Law or Institution policies for the assignment of inventor rights to PHRI.

ARTICLE 7. PUBLICATION

7.1 **Multi-Site Publication By Project Lead:** Site acknowledges that consolidated data from all sites will be analyzed collectively by a Project committee ("**Project Results**"). The Project committee will, regardless of the outcome, submit an initial publication to a peer reviewed, biomedical journal or otherwise make the Project Results public no later than twelve (12) months after the completion of the Project.

7.2 **Single Site Study Publication:** After the Project Results are public, or eighteen (18) months after the conclusion of the Project, Site shall have the right to publish the Study results from the data collected at its location in accordance with the terms of this **ARTICLE 7 (Publication)**. At least sixty (60) days prior to the date for submission of a publication, abstract, and/or presentation ("**Publication**"), Site shall provide copies of any proposed Publication to PHRI/NLO for review and comment by the Project committee. Site agrees to consider the comments, if any, of the Project committee.

7.3 If, in the course of review of the proposed Publication, PHRI/NLO and/or the Project committee identifies any Confidential Information that it or they may wish to protect, PHRI shall have the right to request amendments to the proposed Publication on reasonable grounds including without limitation to: (a) ensure that the proprietary information is not inadvertently divulged, (b) enable intellectual property rights to be secured, and/or (c) enable relevant supplementary information to be provided. Site shall comply with any reasonable request to amend or delete information in a proposed Publication, provided such request does not necessitate removal of Study data and/or results. In addition, on written notice, PHRI may require Site to postpone the Publication to enable PHRI to protect its intellectual property rights. Upon receipt of such written notice, Site shall delay the Publication for the period of time specified in the notice, provided that such period shall not exceed sixty (60) days.

7.4 Other than as agreed herein, no Party shall use the name(s) of another Party or its/his/her Personnel without the prior written consent of such Party. Site may acknowledge in general terms the existence of this Agreement and its receipt of financial support from PHRI in order to comply with Applicable Laws and for Publication of the Study Results, and with the prior written approval of PHRI/NLO in connection with advertising or promotional materials for the Project. PHRI may disclose the name(s) of Site in any Publication of the Project Results and may use the

names and the amount of funding provided to Site for registration of the Project on www.clinicaltrials.gov, www.ctri.in and to comply with Applicable Laws and general industry standards.

ARTICLE 8. DISCLAIMER

8.1 PHRI makes no warranties of any kind whatsoever concerning the efficacy or safety of the Project, the procedures, treatments and medical practices described in the Protocol, the Product, or the Protocol itself. Except as expressly provided herein, PHRI hereby specifically disclaims any and all warranties or conditions, which may be implied by law.

8.2 Site makes no warranties of any kind whatsoever concerning the success of the Study.

ARTICLE 9. INDEMNIFICATION AND INSURANCE

9.1 **PHRI:** PHRI/NLO agrees to defend, indemnify and hold harmless Site and its trustees, directors, officers and Personnel from and against any and all costs, losses, liabilities, damages, actions, proceedings, demands, claims and reasonable expenses including legal fees ("**Claims**") made by a third party to the extent directly resulting from PHRI's/NLO negligence, wrongful acts and omissions in connection with its performance or non-performance of its obligations under this Agreement.

9.2 **Site:** Site agrees to defend, indemnify and hold harmless PHRI/NLO, and its trustees, directors, officers, medical and professional staff, students, appointees, contractors, agents and sponsors (if any) from and against any and all Claims made by a third party to the extent directly resulting from Site's and the Personnel's negligence, wrongful acts and omissions in connection with its performance or non-performance of their obligations under this Agreement.

9.3 **Notification:** In connection with any Claim, each Party shall notify the other Parties promptly of any Claim and cooperate fully in the investigation and defense of any such Claims.

9.4 **Limitation of Liability:** Notwithstanding any other provision of this Agreement, under no circumstances will a Party be liable to another Party for any indirect, consequential or incidental damages that such other Party may have suffered, including without limitation damages for loss of profit or revenue and regardless of whether such other Party has been advised of the possibility of such damages arising, or for non-compensatory damages of any kind, including without limitation aggravated or punitive damages.

9.5 **Insurance:** During the Term and for the duration of their obligations surviving expiration or termination of this Agreement, PHRI and Institution will each obtain and maintain a policy or program of self-insurance at levels sufficient to support their obligations herein and in amounts appropriate to the conduct of their respective businesses, which at minimum, shall include comprehensive general liability coverage with limits of not less than the equivalent of two million dollars Canadian ($2,000,000) aggregate or amounts required by Applicable Laws.

9.6 **Investigator's License:** Investigator agrees to hold membership in the medical professional association in his/her jurisdiction for the duration of the Project and to provide evidence of such membership on PHRI's request.

9.7 NLO shall maintain in force a **clinical trial indemnity insurance** coverage for all Project Subjects recruited in India as required by Applicable Law. A copy of this will be provided to the Institution for reference and production to regulatory / Ethics office. NLO will provide payment to the Institution for reasonable unreimbursed medical expenses, including hospitalization, which the Institution may incur as a direct result of the treatment of a Subject's injuries that directly results from the Product or its administration during the Study, as determined by PHRI and the Investigator.

9.8 **Research Related Injury:** NLO shall be responsible for payment of the reasonable medical expenses incurred in diagnosing and treating any injury, illness, or adverse reaction of a Study

Subject that results from the administration of the Product in accordance with the Protocol or the proper performance of any Protocol procedure.

9.9 A Party shall upon request provide the requesting Party with a copy of the relevant certificate of insurance coverage. As per Indian regulations, the expenses on medical management in case of any injury and financial compensation in case of clinical trial injury or death of the Project Subject shall be borne through the insurance cover undertaken by the NLO. Institution will consider building a contingency fund within the institution to meet the costs immediately and later get them reimbursed from NLO.

ARTICLE 10. TERMINATION

10.1 **For Default:** In the event either PHRI/NLO, on the one hand, or Site, on the other hand, fails to perform or performs improperly any of its material obligations under this Agreement, the non-defaulting Party shall provide the other Party or Parties with thirty (30) days' notice in writing to cure the default. In the event the default is not cured to the reasonable satisfaction of the non-defaulting Party, such Party may terminate this Agreement on notice to the other Parties. Either parties have equal rights to terminate this Agreement.

10.2 **For Safety or Other Reasons:** PHRI/NLO may terminate this Agreement at any time, on written notice to Site if: (a) the regulatory authorization or approval to perform the Project is withdrawn; (b) a decision is made to terminate the Project early due to safety or other reasons; (c) Site has not recruited a Subject into the Study within three (3) months of receipt of notice from PHRI to commence recruitment; or (d) Site is debarred or disqualified. Upon written notice to PHRI/NLO, Site may jointly terminate this Agreement if, in the reasonable judgement of Site, serious or life-threatening events raise issues of subject safety.

10.3 **For No Cause:** PHRI may also terminate this Agreement on thirty (30) days' prior written notice to Site for any reason.

10.4 **On-going Obligations:** Termination shall be subject to the on-going obligations of each of the Parties pursuant to **Section 10.5**. Immediately upon receipt of a notice of termination, Site shall cease recruitment of Subjects into the Study and cease conducting procedures as directed by PHRI and to the extent medically permissible.

10.5 **Closing Activities:** Regardless of the cause of termination, the Parties shall in all instances cooperate in closing-out of the Study and, if applicable, comply with all recommendations of the Project steering committee.

10.6 **Payment:** In the event of early termination of this Agreement, other than for a material breach by Site, PHRI shall pay all fees actually earned to the effective date of termination notice and for closing-out activities as determined by the Project steering committee. PHRI will consider payment of other reasonable non-cancellable expenses incurred by Site, but shall not be liable for such costs or expenses unless they have been pre-approved or subsequently agreed between the Parties.

10.7 **Survival:** The rights and obligations of Parties that by intent or meaning have validity beyond expiration or termination (including, without limitation, rights with respect to intellectual property, Publication, Confidential Information, privacy, and indemnification) shall survive the termination or expiration of this Agreement.

ARTICLE 11. NOTICE

11.1 Any notice required by this Agreement shall be in writing and delivered to the addresses or facsimile numbers specified below or to such other address as each party may from time to time designate to the other in writing. Delivery shall be deemed received as follows - if prior to 4:00 pm on a business day in the jurisdiction of the recipient and otherwise on the next business day by: (a) personal delivery, when delivered personally; (b) courier, upon courier's verification of

delivery; (c) facsimile, successfully received transmission at recipient's location; or (d) electronic mail transmission successfully received by the recipient.

If to PHRI:
Population Health Research Institute
237 Barton Street East
Hamilton, ON L8L 2X2
Canada
Attention: POISE-3 Project Manager
Tel: 905-521-2100 x 40526
Fax: 905-297-3779
Email: shirley.pettit@phri.ca

If to NLO:
The Dean, St. John's Research Institute
a unit of CBCI Society for Medical Education
St. John's National Academy of Health Sciences
Johnnagar, Bangalore
560 034, India
Tel: +91 80 49467001
Fax: +91 80 25501088
Email: deansoffice@sjri.res.in

If to Site (Institution):
Sumandeep Vidyapeeth & Dhiraj General Hospital
General Surgery Department
AT & PO: Piparia, Waghodia Road
Distt-Vadodara, Gujurat, 391760
India
Tel: 91 2668-245262
Fax: 912668-245126
Email: dr.vipulgurjar@yahoo.com

If to Site (Investigator):
Dr. Vipul Gujer
Sumandeep Vidyapeeth & Dhiraj General Hospital
General Surgery Department
AT & PO: Piparia, Waghodia Road
Distt-Vadodara, Gujurat, 391760
India
Tel: 9825470800
Fax: 912668-245126
Email: dr.vipulgurjar@yahoo.com

With copy marked to:
Dr. Denis Xavier
Head - Division of Clinical Research & Training
St. John's Research Institute
St. John's National Academy of Health Sciences
Johnnagar, Bangalore-560 034, India
Tel: +91 80 49466140, +91 80 4946010, +91 80 49467080
Fax: +91 80 49467090
Email: denis@sjri.res.in

11.2 Where any notice is given to PHRI under this Agreement in relation to any alleged breach or default of this Agreement by PHRI or any Claim against PHRI, Site shall also provide the notice to:

Research Counsel
Population Health Research Institute
237 Barton Street East
Hamilton, ON L8L 2X2
Canada
Fax: 905-296-2369
Email: phri.contracts@phri.ca

ARTICLE 12. CONCLUDING PROVISIONS

12.1 **Entire Agreement, Amendment and Assignment:** The Exhibits and the Protocol are incorporated herein by reference and form part of this Agreement. This Agreement sets forth the entire agreement and understanding of the Parties as to the subject matter herein. Any amendments or modifications to this Agreement shall be in writing and signed by authorized representatives of each Party. Institution and/or Investigator may not assign this Agreement or any obligation hereunder without the prior written consent of PHRI/NLO.

12.2 **Recitals:** The Parties acknowledge the foregoing recitals to be true and correct.

Sumandeep Vidyapeeth • Deemed University •

St. John's Research Institute Bangalore

SUMANDEEP VIDYAPEETH

CBCI Society for Medical Education Secretary Bangalore-34

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12.3 **Conflict:** In the event of any conflict between this Agreement and the Protocol, this Agreement will govern for any non-clinical matters and the Protocol will govern for any scientific and clinical matters.

12.4 **Independent Contractors:** As between PHRI/NLO on the one hand, and Site and the Personnel on the other hand, the work performed pursuant to this Agreement shall be as independent contractors and not as partners, joint venturers, employees, subcontractors or agents. No Party has the power or authority to bind another Party.

12.5 **Force Majeure:** In the event that performance of a Party's obligations are prevented by events beyond its reasonable control, including but not limited to, acts of God, regulations or acts of any governmental authority, war, civil commotion, strikes, other labor disturbances, epidemics, fire, earthquakes, storms or other catastrophes of a similar nature, the affected Party will notify the other Parties as soon as reasonably possible and the affected Party shall be relieved of its obligations for the duration and to the extent the performance of an obligation is prevented thereby. During the existence of any such condition, the affected Party shall use diligent efforts to remove the cause and resume performance of its obligations.

12.6 **Governing Law & Jurisdiction:** The interpretation and construction of this Agreement shall be governed by the laws of India excluding any conflicts or choice of law rule or principle that might otherwise refer construction or interpretation of this agreement to the substantive law of another jurisdiction. The Parties hereby irrevocably and unconditionally consent to the exclusive jurisdiction of the courts where the cause of action arises for any action, suit or proceeding (other than appeals therefrom) arising out of or relating to this Agreement, and agree not to commence any action, suit or proceeding (other than appeals therefrom) related thereto except in such courts.

12.7 **Invalidity:** The invalidity or unenforceability of any provision of this Agreement shall not affect the validity of any other provision hereof. The Parties shall make commercially reasonable efforts to replace any invalid or unenforceable provision with one that is valid and enforceable, and reflects the originally intended commercial objectives of the Parties.

12.8 **Signing:** This Agreement may be signed in any number of counterparts, each of which so executed is deemed to be an original and when joined together constitute one and the same original agreement. The Parties agree that fax or electronic copies have the same effect as original hardcopies.

- signature page to follow -

IN WITNESS WHEREOF, the Parties have executed this Agreement as of the Effective Date.

Hamilton Health Sciences Corporation

Signature
Name: Beena Cracknell
Position: Director, **Financial Services**, Population Health Research Institute

Date: 2019-MAR-06
(YYYY-MMM-DD)

INVESTIGATOR

Signature
Name: Dr. Vipul Gujer

Date: 2019-May-31
(YYYY-MMM-DD)

INSTITUTION: Sumandeep Vidyapeeth & Dhiraj General Hospital

Signature
Name: Dr. Chandraman[illegible] More
Title: Registrar.

Sumandeep Vidyapeeth • Deemed University •

Date: 2019 July 10
(YYYY-MMM-DD)

On Behalf of CBCI

SECRETARY
C.B.C.I. SOCIETY FOR MEDICAL EDUCATION
ST. JOHN'S NATIONAL ACADEMY OF HEALTH SCIENCES
SARJAPUR ROAD, BANGALORE - 560 034

Signature
Name:
Title:

Date: 2019 May 22
(YYYY-MMM-DD)

On behalf of St. John's Research Institute

Signature
Name:
Title:

DEAN
St. John's Research Institute
St. John's National Academy of Health Sciences
Koramangala, Bangalore - 560 034, INDIA

Date: 2019 MAY 20
(YYYY-MMM-DD)

On behalf of NLO

Signature
Name: Dr. DENIS XAVIER, MD, M.Sc.
Title: Vice Dean (PG)
Professor of Pharmacology
St. John's Medical College
Bengaluru - 560 034, India.

Date: 2019 Apr 10
(YYYY-MMM-DD)

SUMANDEEP VIDYAPEETH

EXHIBIT 1 – PAYMENT SCHEDULE

Payment will be in **CAD and will be converted to rupees using the exchange rate as of the date of processing**. Payments will be processed on a quarterly basis with payment run cut-offs on March 31st, June 30th, September 30th and December 31st of each year. Payments will be issued within 25 days from the processing/run date (i.e., payment for run date March 31st is mailed on or prior to April 25th). Payments will be made for all CRFs received and validated to be clean prior to the run date, according to the payment schedule.

The fee per subject is inclusive of all costs (i.e. staff time, study lab investigations, event reporting costs, archiving costs, institutional overheads, cost to purchase TXA and any dispensation fees, participant expenses such as travel and parking, all applicable taxes including VAT or its equivalent).

Enrolment and Follow-up:

Visit Type	Amount in CAD per Study Subject, per visit and receipt of all required CRFs for the visit
Randomization Visit	75
Baseline	40
Hospital Discharge	50
1 Month	25
1 Year	40
Holdback fee *	20
Total Per Patient Fee (CAD) **	**250**

* Holdback fee will be paid after database lock if all required data for the participant has been collected and provided to PHRI prior to database lock.

** The actual fees paid will be based on completion of visits and collection of all required data.

Additional Payments for Product management at site:

Product management support fees will be provided as installments based on successful randomization of the first Study Subject and subsequent recruitment rate at Site towards various Study activities that will be required to be completed by the Site.

Subjects recruited	Amount in CAD
1st Subject recruited	200
20th Subject recruited	200
40th Subject recruited	200
50th Subject recruited	200

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SUMANDEEP VIDYAPEETH

C.B.C.I. SOCIETY FOR MEDICAL EDUCATION Secretary BANGALORE-34

EXHIBIT 2 – PAYMENT RULE FORM

COUNTRY:	**INDIA**
CENTRE #:	**468**
INSTITUTION:	**Sumandeep Vidyapeeth & Dhiraj General Hospital**
INVESTIGATOR:	**Dr. Vipul Gurjar**

Payment will be in **CAD and will be converted to rupees using the exchange rate as of the date of processing**. Payments **will be** processed on a quarterly basis with the payment run cut-offs on March 31st, June 30th, **September 30th and** December 31st of each year. Payments will be issued and sent out within 25 days **from the processing/run** date (i.e., payment for run date March 31st will be sent on or prior to April 25th) **provided that a minimum of 500 CAD** has been earned within such payment period. Payments **will be made for all** CRFs received and validated to be clean prior to this date, according to the attached **payment schedule.**

Payments will be made to only one party. **(ALL INFORMATION BELOW MUST BE PRINTED)**

The following information is required in order to generate payment by wire transfer. Incomplete information could result in delay in payment.	
Bank Name:	AXIS BANK LIMITED
Bank Address:	SWASTIK VALUE HEIGHTS, PLOT NO. NDR 23, TILAK NAGAR, CHEMBUR (WEST), MUMBAI - 400 089.
Bank SWIFT code:	AXISINBB029
Beneficiary Name:	RAV Research Private Limited.
Beneficiary Address:	2A/2, Shree Gokul CHS, Vrindaban Society, Thane (W) - 400601, Maharashtra, India.
Beneficiary IBAN or Account number:	916020026214021
IFSC Code (if applicable):	UTIB0001155
Reference (if applicable):	NIL
Contact name and email of person generating the invoice (if applicable):	Dr. Vikas Gujar (email.: researchrav@gmail.com)

The information below is required before PHRI can initiate any payment.

Are you an entity that has to submit value added tax? √ Yes ___ No Tax rate: 18%
If payment to the Investigator please provide following:
Social Security (US)/Social Insurance Number (Canada) or other applicable personal income tax identifier #:
Investigator First Name, Middle Initial and Last Name: **Vipul P Gurjar**
If payment to a business entity such as the Investigator's professional corporation or the Institution please provide the following:
Tax ID #/GST Registration #: 27AAHCR6102L2Z7
PAN card #: AAHCR6102L
For HHSC use only – Vendor ID #:

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Attested CTC

30/11/2023

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