हरियाणा HARYANA

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MGM Medical College, Navi Mumbai

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M.G.M. Medical College & Hospital
Kamothe, Navi Mumbai - 410209

OUS Templates
OUS LOA
Revised: 07 2017

17-May-2018

Dr. Hemangi Jerajani
Professor and Head, Department of Dermatology
MGM Institute of Health Sciences
3rd Floor, Sector-1, Kamothe
Navi Mumbai - 410209

Dear Jerajani:

This agreement ("Agreement") is by and between Eli Lilly and Company (India) Pvt. Ltd.("Lilly"), **AND Dr. Hemangi Jerajani,** Professor and Head, Department of Dermatology, as the principal investigator ("Investigator"), **of MGM Institute of Health Sciences, 3rd Floor, Sector 1, Kamothe, Navi Mumbai - 410209** ("Institution") for the performance of the study ("Study) entitled "A Multicenter, Randomized, Double-Blind, Placebo-Controlled, Phase 3 Study to Evaluate the Efficacy and Safety of Baricitinib in Adult Patients with Moderate to Severe Atopic Dermatitis," protocol **I4V-MC-JAHL** ("Protocol"), which Protocol is incorporated herein by reference. Investigator is an independent contractor of Institution with privileges to use Institution's facilities and resources. This agreement ("Agreement") sets forth the obligations of Lilly, the Investigator and Institution.

I. YOUR OBLIGATIONS

Investigator and Institution agree to assume the following obligations in executing this Agreement:

A. Conduct of the Study

Investigator and Institution agree that Investigator will personally conduct or supervise the Study at Institution and any Lilly-approved sub-sites or satellite sites (collectively "Study Sites"), if applicable. Investigator and Institution agree that Investigator and Institution will not use sub-sites or satellite sites in the conduct of the Study unless Lilly has given written approval for use of the sub-sites and satellite sites. If any portion of the Study is performed by Investigator or a sub-investigator at a facility or hospital other than Institution, Investigator and/or Institution shall be responsible for ensuring that any such Study Site is aware that it is involved in the Study and consents to such participation. Investigator and Institution (and colleagues, including sub investigators) agree to comply with the following: all conditions specified in the Protocol and Protocol amendments and/or addenda; Good Clinical Practice Guidelines; the approval of Ethical Review Board ("ERB"); and all other applicable national, state and local laws, regulations and standards. Investigator and Institution shall ensure that all of sub investigators, associates, colleagues and employees involved in the conduct of the Study at Study Sites also understand and agree to comply with these obligations and the provisions of this Agreement.

In carrying out Investigator and Institution's responsibilities under this Agreement, Investigator and Institution agree to comply with all applicable anti-bribery laws in the countries where Investigator and Institution have Institution's principal place of business and where Investigator and Institution conduct activities under this Agreement. Additionally, Investigator and Institution understand and agree to comply with the U.S. Foreign Corrupt Practices Act, as revised, which generally prohibits the offer, promise, payment or giving of anything of value either directly or indirectly to any government official for the purpose of obtaining or retaining business or any improper advantage. For purposes of this section, "government official" means any official, officer, representative, or employee of, including any doctor employed by, any non-U.S. government department, agency or instrumentality (including any government-owned or controlled commercial enterprise), or any official of a public international organization or political party or candidate for political office. Additionally, if Investigator and Institution or any of Institution's owners, directors, employees, agents, and consultants are government officials, Investigator and Institution agree that Lilly's payment of Investigator and Institution in connection with this Agreement is not intended to influence any decision that any individual may make in their capacity as a government official. Investigator and Institution further represent that neither Investigator and Institution nor any of Institution's owners, directors, employees, agents, or consultants will directly or indirectly offer to pay, promise to pay or give anything of value to any government official for purposes of (i) influencing any act or decision of such government official in his official capacity; (ii) inducing such government official to do or omit to do any act in violation of the lawful duty of such official; (iii) securing any improper advantage; or (iv) inducing such government official to use his influence with the government or instrumentality thereof to affect or influence any act or decision of the government or such instrumentality with respect to any activities undertaken relating to this Agreement. Additionally, Investigator and Institution will make reasonable efforts to comply with requests for information, including answering questionnaires and narrowly tailored audit inquiries, to enable Lilly to ensure compliance with applicable anti-bribery laws. Investigator and Institution agree that Lilly's payment to Investigator and Institution in connection with the services to be provided under this Agreement is not intended to influence any decision Investigator and Institution may make regarding the prescription of Lilly medicines or to otherwise influence any pending or future Lilly business.

Investigator and Institution shall also ensure that each investigator and sub-investigator at Institution'sStudy Site (s) provides Lilly with the appropriate financial information for compliance with all applicable laws and regulations and Lilly policy, and Investigator and Institution understand and shall ensure that each investigator and sub-investigator understands that laws, regulations and Lilly policy may require certain financial information to be submitted to regulatory authorities.

If Investigator is not a licensed physician, Investigator and/or Institution shall ensure that a licensed physician is an investigator or sub-investigator at Study Site (s) and will be responsible for patient care and other appropriate aspects of this Study.

Investigator acknowledges that Investigator has read and understands all information in the investigator's brochure provided to Investigator by Lilly, including the potential risks and side effects of the Study drug.

Investigator and Institution agree not to pay fees to another physician for the referral of patients.

Investigator and Institution agree to only use an informed consent document which has been reviewed and approved by Lilly.

Investigator and Institution agree that Lilly, Lilly-designated representatives and domestic or foreign regulatory agencies may inspect procedures, facilities and Study records (including portions of other pertinent records for all patients in the Study) and those procedures, facilities or Study records of any contractor, agent Study Site (s) used in conducting the Study. Investigator and Institution shall provide Lilly with immediate notice of any governmental or regulatory review, audit or inspection of the facility or processes related to the StudyLilly shall be given the opportunity to provide assistance to Investigator and Institution in responding to any such review, audit or inspection.Investigator and Institution shall provide Lilly with the results of any such review, audit or inspection. When data are reviewed by an on-site scheduled visit of a Lilly-designated representative, Investigator and/or Institution will have all reasonably available data obtained through the preceding day complete and ready for evaluation. Information obtained from such inspections may be shared with Lilly and Lilly-designated representatives. In the event that there is a lack of compliance with this Agreement, Lilly is entitled to secure compliance or discontinue shipments of Study drug and end Investigator and/or Institution's participation in the Study.

B. Clinical Trial Materials and Record Retention

Drugs furnished for the Study will be used solely under the Protocol and may not be used for any other purposes. Investigator and Institution shall follow Lilly's instructions related to disposition of clinical trial materials. Investigator and Institution shall be responsible for compliance with all laws and regulations applicable to any destruction or disposition of clinical trial materials at Study Site(s). All Study records must be retained for fifteen (15) years after completion or termination of the Study, provided, however, that in the unlikely event that ICH or FDA record retention requirements, (i.e., two (2) years after the date of marketing application approval by FDA for the Study drug(s) indication investigated, or if an application is not approved, two (2) years after the FDA is notified by Lilly of discontinuation of the IND) are longer than fifteen (15) years, Lilly will notify Investigator and Institution regarding any additional length of time that records must be

retained to meet such requirements. The Investigator and/or Institution agree to take the appropriate measures to prevent premature destruction of essential documents.

C. Confidentiality and Non-Use

All information provided to Investigator and/or Institution by Lilly or Lilly-designated representatives, or generated by Investigator and/or Institution in connection with the Study, will be kept in confidence and not used for any purpose not expressly provided for in this Agreement for at least five (5) years after the termination or conclusion of the Study, except to the extent that Lilly gives Investigator and/or Institution written permission or particular information is required by laws or regulations to be disclosed to the ERB, the patient or local regulatory agencies. To the extent disclosure is requested by any other person or entity, Investigator and/or Institution shall promptly notify Lilly and shall not disclose any information without Lilly's prior written consent. If such disclosure is sought by a third party under a claim of legal right, Investigator and/or Institution will reasonably cooperate with Lilly in the event Lilly wishes to take legal action to challenge such claim or the disclosure; provided, however, in no event shall Investigator and/or Institution be obligated to defy any law, regulation or judicial or governmental order.Investigator and Institution shall be responsible for ensuring that their employees, sub investigators, contractors and agents are obligated to these same terms of confidentiality and non-use. The terms of confidentiality and non-use set forth herein shall supersede any prior terms of confidentiality and non-use agreed to by the parties in connection with this Study. The terms of this Agreement shall also be considered confidential information and may be disclosed only to the extent required by law or necessary for approval of this Study.Additionally, in the event Investigator is invited to be an author of a Lilly publication or presentation during the course of or after the conclusion of the Study covered by this Agreement, Investigator and Institution agree that they will hold all new information (including data from other investigator sites for multi-site studies) provided to Investigator or Institution by Lilly or Lilly-designated representatives, or generated by Investigator or Institution in connection with such authorship, in confidence for five (5) years from the date of such disclosure or the generation of information, as applicable. This obligation survives the expiration, cancellation or termination of this Agreement.

The foregoing obligations of confidentiality and non-use will not apply to information that:

(1) is or later becomes part of the public domain other than through Investigator or Institution's act or omission;

(2) was known by Investigator and/or Institution prior to disclosure by Lilly or becomes known from an independent source or third party under no obligation to Lilly or any other third party to keep such information confidential, as can be shown by prior written documentation; or

(3) is independently developed, as shown by written documentation, by Investigator or Institution or their personnel who have not had access to confidential information provided by Lilly.

D. Data

Data generated in connection with the Study, excluding patient medical records not recorded as case report forms, shall be the sole property of Lilly and shall be subject to the obligations of Confidentiality and Non-Use set forth above.

E. Publications

Notwithstanding the obligations of Confidentiality and Non-Use set forth above, Investigator and Institution will be free to publish and present the results of the Study subject to the following conditions: Lilly will be furnished with a copy of any proposed publication or presentation for review and comment thirty (30) days prior to such presentation or submission for publication. Such thirty (30) day period does not begin until receipt of the proposed publication or presentation at Lilly in Indianapolis, Indiana. At the expiration of such thirty (30) day period, Investigator and/or Institution may proceed with the presentation or submission for publication; provided, however, that in the event Lilly has notified Investigator or Institution in writing that Lilly reasonably believes that prior to such publication or presentation it must take action to protect its intellectual property interests, such as the filing of a patent application claiming an invention or a trademark registration application, Investigator and/or Institution shall either (1) delay such publication or presentation for an additional sixty (60) days or until the foregoing action(s) have been taken, whichever shall first occur; or (2) if Investigator and/or Institution are unwilling to delay the publication or presentation, Investigator and/or Institution will remove from the publication or presentation the information which Lilly has specified it reasonably believes would jeopardize its intellectual property interests. Under certain circumstances, a shorter review period may be granted in writing by Lilly. Investigator and/or Institution will assist Lilly in obtaining reprints of Investigator or Institution's publication(s) resulting from the Study.

F. Inventions

If during the course of the Study or within one (1) year after termination of this Agreement, Investigator and/or Institution conceive or actually reduce to practice what Investigator and/or Institution believe to be a new invention (including, without limitation, new uses, processes, formulations, therapeutic combinations or methods) occurring as a result of the performance of the Study covered by this Agreement or involving the Study drug(s), device(s), or simple derivatives of the Study drug(s) (e.g. but not limited to, antibody fragments, analogs, salts, solvates, conformers, stereoisomers, racemic mixtures, amorphous forms, crystal forms, crystal habits, metabolites, prodrugs, free acids, chelates, complexes, synthetic intermediates, isotopic or radiolabeled equivalents or mixtures thereof), Investigator and/or Institution shall promptly notify Lilly. The new invention or use shall be the sole property of and shall be assigned to Lilly.

G. Publicity

Consistent with the obligations of Confidentiality and Non-Use set forth above Investigator and/or Institution agree to the following:

(1) Solicitation of patients. Lilly and the ERB must approve, in writing, the text of any communication soliciting patients for the Study before placement, including, but not limited to, newspaper and radio advertisements, direct mail pieces, internet advertisements or communications and newsletters. Such communications must comply with applicable laws and guidelines.

(2) Press releases. Lilly must approve, in writing, press statements by Investigator and/or Institution regarding the Study or the Study drug(s) before the statements are released.

(3) Inquiries from media and financial analysts. During and after the Study Investigator and Institution may receive inquiries from reporters or financial analysts. Investigator and Institution agree to confer with Lilly's Research Physician or Medical Director at +91-124-4753000 or Lilly's Corporate Communications Department in the United States at (001-317-276-3402) to discuss such inquiries before responding to them.

(4) Use of name. Neither Lilly nor Investigator and Institution will use the name or names of the other party or their employees in any advertising or sales promotional material or in any publication without prior written permission; provided, however, Investigator and Institution agree to the use of their names in Study publications and communications, including clinical trial web sites and Study newsletters and Lilly may disclose Investigator and Institution's name and the names of any sub-investigators, the type of services performed by Investigator and Institution and and/or any sub-investigator for Lilly under this Agreement, the existence and terms of this Agreement, and the amount of compensation Lilly paid in exchange for Investigator and Institution's services or the services of any sub-investigator, in order to comply with applicable laws and regulations.Investigator and Institution shall be responsible for ensuring that all sub-investigators have consented to these same terms of disclosure.

H. Debarment Certification (Generic Drug Enforcement Act of 1992)

Investigator and Institution agree that they are not and have not been debarred or disqualified from participating in clinical research by any United States regulatory authority or by any other regulatory authority, and that they will not use or involve any person or organization in connection with this Study that is or has been debarred or disqualified by any regulatory authority from participating in clinical research. In the event that Investigator and/or Institution or any person or organization they use or involve in connection with the Study should become debarred or disqualified during the course of the Study, Investigator and/or Institution agree to promptly notify Lilly in writing.

I. Contract Research Organization Involvement

Lilly shall be entitled to authorize a contract research organization to perform certain sponsor obligations for this Study. Investigator and Institution agree to cooperate with any Lilly-authorized contract research organization in performing this Study.

J. Equipment

Lilly is providing Investigator and/or Institution with equipment ("Equipment") for use in the Study. Investigator and Institutionagree to comply with all manuals and instructions from Lilly regarding the use and care of the Equipment. Investigator and Institution agree that the Equipment shall remain in the same condition, ordinary wear and tear excepted, and that Investigator and Institution shall be responsible for the Equipment including the maintenance or any risk of loss in connection with the Equipment during the term of the Study. Investigator and Institution will follow Lilly's instructions for disposition of the Equipment at the completion or termination of the Study.

K. Site Personnel Data

Lilly may collect personal information from Investigator and Institution personnel including but not limited to names, titles and business contact information ("Site Personnel Data") and may provide that information to Lilly's business partners and vendors working with Lilly on matters related to the Study to fulfill Lilly's business purposes, including:

(1) Compliance with laws and regulations regarding possible financial conflicts of interest;
(2) Assessment of personnel qualifications to conduct the Study;
(3) Quality control and Study management; and
(4) Disclosures to ERBs, Ethics Committeesor national or foreign regulatory authorities in connection with their performance of review or oversight responsibilities for the Study.

Site Personnel Data may also be aggregated with data from other Lilly sources and evaluated for business decisions including those involving future research. Lilly may store or process such Site Personnel Data in the U.S. or other countries at Lilly or Lilly-associated facilities, as long as a business need or legal obligation exists.

Investigator and Institution personnel may have access to Site Personnel Data about themselves that Lilly has collected and may have corrections made to Site Personnel Data about themselves that is inaccurate. Investigator and Institution agree to obtain the permission of their personnel for the transfer and use of Site Personnel Data for the purposes described in this section

Investigator and Institution may contact Lilly with inquiries regarding Lilly's collection or use of Site Personnel Data. Lilly agrees to comply with all applicable laws and regulations regarding Lilly's use of Site Personnel Data.

II. LILLY SUPPORT

Lilly will provide Investigator and/or Institution with Study drug(s) and/or device(s) as applicable to the Study. In addition, Lilly will provide financial support for the Study as follows:

A. Payee
Payment in connection with the Study will be made to the name and address listed below:

Payee: MGM Institute of Health Sciences

Address:MGM Institute of Health Sciences

3rd Floor, College Building, Sector 1, Kamothe, Navi Mumbai - 410209

PAN: AACTM0014C
(Identification Number for Tax Purposes)

B. Payment Schedule
In connection with the Study, Institution will be paid in accordance with the terms set forth in the budget ("Budget"), attached hereto as Exhibit A. For those amounts designated for patient services, Institutionwill receive payment only for data received based on the actual number of visits and procedures performed in accordance with agreed upon procedure fees outlined in the Budget. Such compensation is limited to payment for the number of patients designated in the Budget who are enrolled in the Study by **30-Dec-2018**, unless Lilly givesInvestigator or Institution written approval to enroll additional patients or extend the enrollment period. In the event that such approval is granted, Institution will be paid in accordance with the fees set forth in the Budget for the additional

patients.Other than the final payment, Lilly shall not issue any payment for a total amount less than INR 1,000 (Rupees One Thousand Only). In the event the amount due in any given period is less than INR 1,000 (Rupees One Thousand Only), such amount shall carry over without payment to the next payment period. In addition to the payments set forth above, Lilly will also reimburse Payee for reimbursable expenses as set forth in the Budget.

To be eligible for payment, all procedures must be performed in full compliance with the Protocol and this Agreement, and the data submitted must be complete and correct. For data to be complete and correct, each patient must have signed an ERB-approved consent document, and all procedures designated in the Protocol must be carried out on a "best efforts" basis; omissions must be satisfactorily explained. Final payment will be made by Lilly to the Payee when all patients at the Site have completed the Study and upon final acceptance by Lilly of all CRFs pages, all data clarifications issued, the receipt and approval of any outstanding regulatory documents as required by Lilly, the return of all unused supplies to Lilly, and upon satisfaction of all other applicable conditions set forth in this Agreement.It is expected that for all items required under the Protocol for which Lilly has agreed to provide compensation, Lilly will be the sole source of compensation. Institution will not seek payment from any third party payor, whether public or private, for any costs covered by payments made by Lilly under this Agreement. Matters in dispute shall be payable upon mutual resolution of such dispute.

When Investigator and/or Institution data are reviewed by an on-site scheduled visit of a Lilly-designated representative, Investigator and/or Institution will have all reasonably available data obtained through the preceding day complete and ready for evaluation. Lilly reserves the right to refuse payment for data not received by Lilly within ten (10) days after the representative's review.

In addition, if Lilly requests Investigator and/ or Institution attendance at a Study startup meeting or other meeting necessary to provide Investigator and/or Institution information regarding the Study or Study drug, Lilly shall reimburse Institution for reasonable and necessary travel and lodging expenses (including meals) that are incurred to attend such meeting(s) that have been specifically approved in advance by Lilly. Lilly shall make such reimbursements within thirty (30) days of receiving acceptable detailed documentation of such expenses, provided that Lilly receives such documentation within sixty (60) days of the date that the expenses were incurred.

C. Subject Injury Reimbursement

Lilly agrees to reimburse Institution for the following additional costs:

(1) All reasonable and customary costs incurred and associated with the diagnosis of an adverse event involving the Study drug or a Protocol procedure; and

(2) All reasonable and customary costs incurred for treatment of physical injury to the subject if Lilly determines after consulting with Investigatorthat the adverse event was reasonably related to administration of the Study drug or Protocol; provided, however, that:

(a) such costs are not covered by the subject's medical or hospital insurance or other governmental program providing such coverage;

(b) the adverse event is not attributable to Investigator and/or Institution or any of their agents' or employees' negligence or misconduct;

(c) the adverse event is not attributable to any underlying illness, whether previously diagnosed or not; and

(d) Investigator and Institution have adhered to and complied with the specifications of the Protocol and all recommendations furnished by Lilly for the use and administration of any drug or device used in the Study.

Lilly shall have the option of paying the additional costs directly to the provider of the service or to Institution.

D. Limit of Patient Entry or Enrollment and Study Termination

Lilly reserves the right to limit entry or enrollment of additional patients at any time. This may occur in a competitive-enrollment Study because sufficient patients have been entered by other investigators to complete the needs of the Study. Lilly also reserves the right to terminate Investigator, Institution or any patient's participation in the Study or the Study itself at any time for any reason. Investigator and/or Institution may terminate the Study upon thirty (30) days written notice in the event (1) there is a breach of a material provision of this Agreement by Lilly, which breach is not cured by Lilly within ninety (90) days following receipt from Investigator and/or Institution of written notice thereof; (2) if the Investigator becomes unavailable due to death or disability and Institution and Lilly are unable to agree upon an acceptable replacement; or (3) if the authorization and approval to perform the Study is withdrawn by any local regulatory authority, any United States regulatory authority or by the ERB. In the event Investigator and/or Institution's participation in the Study or the Study itself is terminated, Investigator and/or Institutionagree to return, retain or dispose of all Study drug(s) in accordance with instructions to be provided by Lilly and regulatory requirements.

In the event of termination, payments will be made for all work that has been performed up to the date of termination and shall be limited to reasonable non-cancelable costs which were incurred by Investigator and/or Institution in connection with the Study as required under the Protocol and contemplated in the Budget. If any paymentsexceed the amount owed for work performed under the Protocol, Investigator and/or Institution agree to return the excess balance to Lilly.

III. INDEMNIFICATION

In consideration of the performance by Investigator, Institution and their staff, officers, agents and employees ("Indemnitees") of the Study, Lilly agrees to indemnify, defend and hold harmless the Indemnitees from and against loss, damage, cost and expense of claims and suits (including reasonable legal fees) resulting from an injury to a patient seeking damages alleged to have been directly caused or contributed to by any substance or procedure administered in accordance with the Protocol, including the cost and expense of handling such claims and defending such suits; provided, however, (1) that Indemnitees have adhered to and complied with all applicable federal, state and local regulations (including, without limitation, obtaining informed consents and IRB approvals), the specifications of the Protocol and all recommendations furnished by Lilly for the use and administration of any drug or device described in the Protocol; (2) that Lilly is promptly notified of any such claim or suit; (3) that the Indemnitees cooperate fully in the investigation and defense of any such claim or suit; (4) that Lilly retains the right to defend the lawsuit in any manner it deems appropriate, including the right to retain

counsel of its choice; and (5) that Lilly shall have the sole right to settle the claim or suit; provided, however, that Lilly shall not admit fault on Indemnitees' behalf without Indemnitees' advance written permission. In addition, Lilly's obligation of indemnification shall not extend to any loss, damage or expense arising from the negligence, willful malfeasance or unlawful act or malpractice by the Indemnitees, it being understood that the administration of any substance in accordance with the Protocol shall not constitute negligence, willful malfeasance or unlawful act or malpractice for purposes of this Agreement.

IV. SURVIVORSHIP CLAUSE

The obligations under the sections INVESTIGATOR AND INSTITUTION OBLIGATIONS, SUBJECT INJURY REIMBURSEMENT and INDEMNIFICATION shall survive the expiration, termination or cancellation of this Agreement.

V. INDEPENDENT CONTRACTOR

Institution and Lilly will be acting as independent contractors and not as an agent, partner or employee of the other party. Neither Institution nor Lilly will have any authority to make agreements with third parties that are binding on the other party.

By signing this Agreement, Investigator and Institution represent and warrant thatthey have the authority and ability to or will otherwise contractually bind any individual or entity who performs services for Investigator and Institutionin connection with the Study hereunder to the terms and conditions of this Agreement. This Agreement is legally binding when, but not until, each party has received from the other a counterpart of the Agreement signed by the authorized representative. The parties' representatives may sign separate, identical counterparts of this document; taken together, they constitute one agreement. A signed counterpart may be delivered by any reasonable means, including facsimile or other electronic transmission. Additionally, the parties agree that facsimile or email copies of this Agreement are considered to be a legal original and signatures thereon shall be legal and binding agreement.

This Agreement represents the entire understanding between the parties and supersedes all other agreements, express or implied, between the parties concerning the subject matter hereof. This Agreement has been thoughtfully considered by the parties and, consequently, shall not be strictly construed against either party. This Agreement shall be interpreted in accordance with the laws of India (Haryana Jurisdiction).

Exhibit A:JAHL

S. No.	Investigations	No of Visits	Cost/frequency INR (Y)	Total Amount (X*Y*Z)
1.	**Principle Investigator Fee:** @Rs. 4000/- per patient clinic visit x 9 visits for 10 enrolled patients **(Z)**	Total-9 visits (Visits-1, 2, 3, 4, 5, 6, 7, 8/ED, 801)	4000	360,000
2.	**Co-Investigator Fee:** @ Rs. 2500/- patient clinic visit x 9 visits for 10 enrolled patients	Total-9 visits (Visits-1, 2, 3, 4, 5, 6, 7, 8/ED, 801)	2500	225,000
3.	**Study Coordinator Fee:** @ Rs. 1500/- per patient clinic visit x 9 visits for 10 enrolled patients	Total 9 visits (Visits-1, 2, 3, 4, 5, 6, 7, 8/ED, 801)	1500	135,000
4.	**Phlebotomist Fee** @ Rs. 700/- per patient clinic visit x 7 visits for 10 enrolled patients	Total 7 Visits (Visits-1, 2, 5, 6, 7, 8/ED, 801)	700	49,000
5.	**Patient Inconvenience** including TDS @ Rs. 1111/- per patient x 9 clinic visits x10 enrolled patients	Total-9 visits (Visits-1, 2, 3, 4, 5, 6, 7, 8/ED, 801)	1111	99,990
6.	**Institutional Grant** 20% of PI+ Co-I + SC fees	Total-9 visits (Visits-1, 2, 3, 4, 5, 6, 7, 8/ED, 801)	1600	144,000
7.	**Admin grant** @ Rs. 444 per visit x 9 clinic visits x 10 enrolled patients	Total-9 visits (Visits-1, 2, 3, 4, 5, 6, 7, 8/ED, 801)	444	39,960
8.	**Chest X-Ray** @ Rs.300/- x 1 visit for 10 enrolled patients	Visit 1	300	3,000
9.	**12-lead ECG** (performed and read locally) @ INR 300/-per patient on visit 1 for 10 enrolled patients	Visit 1	300	3,000
10.	Initial Admin Grant paid after Site initiation visit		30,000	30,000
11.	Final Admin Grant paid after data base lock		30,000	30,000
			Total Grant for 10 Patients	**11,18,950**
12.	Screen Failure Cost (Assume 10 pts)	Visit 1	12,455	1,24,550
13.	Pre-Screening Reimbursement @ INR 1000 per identified patient in pre-screening log for upto 30 patients		1000	30,000

Exhibit B: Payment Schedule

The payments will be made per patient visit entered into the data management system (based on the investigation schedule and cost outlined in the table number 1, unless indicated otherwise, as per the following table:

S. No.	Particulars	Cost INR
Total Payment for each visit inclusive of 20% institutional Grant on PI, Co-I, CRC fees		
1.	Visit 1 & Screen Failures	12,455
2.	Visit 2	11,855
3.	Visit 3	11,155
4.	Visit 4	11,155
5.	Visit 5	11,855
6.	Visit 6	11,855
7.	Visit 7	11,855
8.	Visit 8	11,855
9.	Visit 801	11,855
10.	Early discontinuation Visit	11,855

Exhibit C: Procedural Payments

S. No.	Procedure at Local Lab	Visit	Cost of Procedure	Total Amount for 10 pts
1.	**Urine Pregnancy test** @ Rs.300/- x 7 visit for 10 enrolled patients	Total-7 visits (Visit 2, 4, 5,6,7,8,801)	300	21,000
2.	Herpes Zoster Vaccine, provided & administered locally by Site, if required. Up to one vaccine administration per patient			On Actuals
3.	Reimbursement of locally-sourced over-the-counter emollients (up to 500g). Price is per bottle/Tube and requires third-party receipts to be provided.			On Actuals
4.	**Purified PPD TB test** @ Rs.300/- x 1 visit for 10 enrolled patients	Total-1 Visit (Visit 1)	300	3,000
5.	**QuantiFERON®-TB Gold test** @ Rs.4000/- x 1 visit for 10 enrolled patients	Total-1 Visit (Visit 1)	4000	40,000

Descriptions:

- Per Patient budget excluding GST: **INR 1,11,895**
- Site enrollment target (Z): **10 patients**
- Total Budget including Pre-screened patients, Screen failure patients& Procedural Payments:**INR13,37,500**
- Total Budget, including GST: **INR 15,78,250**

Payment Cycle and Procedure:

- Payments will be made on a monthly basis, based on invoices received on or before 5th of every month
- All the visits and procedures included in the invoice must be entered into CRF (Case Report Form) for the payment to be processed
- Payments for Pre-screening will be processed based on the pre-screening logs received from site on weekly basis.

Procedural Payment:

- Procedural payments will be processed and reimbursed on request from the site.
- The procedures performed at site's internal laboratory will be reimbursed based on amount specified in this agreement. A copy of invoice for the procedure is needed in this case.
- The procedures performed at External laboratory will be reimbursed based on amount claimed in invoice. A copy of invoice for the procedure is mandatory in this case.

GST:

- The above mentioned calculation of visit payment does not include GST. GST will be paid as applicable based on the invoices received
- **Eli Lilly India PAN number: AAACE8901F**

Screen Failure Patients:

- The Payment of screen failure patients would be paid on the basis of patients who have signed the ICF and the eCRF data entry for the same has been completed in Electronic Data Management System (INFORM) and as per amount specified for screen failure in Exhibit A (Visit 1).

Patient Reimbursement

- Patient reimbursement amount is inclusive of the TDS amount.

Screen Failure & Early Discontinuation Patients:

- This LOA is valid for a maximum of 30 pre-screened, 10 screen failures & 10 Randomized patients.
- Early Discontinuation fee will be paid if all required procedures as per schedule of events in study protocol have been carried out at a clinic visit by the patient.

Pre-Screening Reimbursement:

- To commence after site has received Ethics Committee approval and this Letter of agreement is fully signed & executed.
- Payable upon weekly receipt of completed Pre-screening Log, for identified subjects based on I/E criteria.
- Frequency of payment will be Monthly.

Kindly note that if final number of patient visits/ lab tests is more or less, addition or deduction respectively would be made to the above grant heads at the rates given against each.