

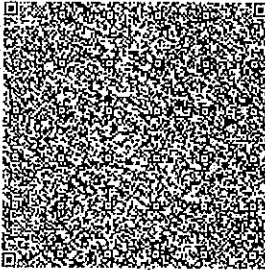


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# INDIA NON JUDICIAL Government of Karnataka

## e-Stamp

Certificate No.	: IN-KA03262010744535P
Certificate Issued Date	: 18-Mar-2017 11:29 AM
Account Reference	: NONACC (FI)/ kaksfcl08/ COX TOWN/ KA-BA
Unique Doc. Reference	: SUBIN-KAKAKSFCL0855290968587626P
Purchased by	: BIOQUEST SOLUTIONS PVT LTD
Description of Document	: Article 12 Bond
Description	: AGREEMENT
Consideration Price (Rs.)	: 0 (Zero)
First Party	: Dr HEMANGI RAJIV JERAJANI
Second Party	: BIOQUEST SOLUTIONS PVT LTD
Stamp Duty Paid By	: BIOQUEST SOLUTIONS PVT LTD
Stamp Duty Amount(Rs.)	: 100 (One Hundred only)



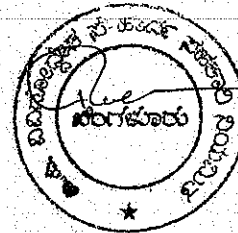
*[Signature]*

Dean

MGM Medical College, Navi Mumbai

Dean.

MGM Medical College & Hospital  
Sector 18, Kamothe, Navi Mumbai - 410209



Dr. Rajesh B. Goel  
Registrar

MGM Institute of Health Sciences  
(Deemed University) via J of UGC  
Navi Mumbai-410 209

-----Please write or type below this line-----

## OBSERVATIONAL STUDY SITE AGREEMENT

This Observational Study Site Agreement ("Agreement"), having an effective date of 18-Mar-2017 ("Effective Date"),  
between

**Dr. Hemangi Rajiv Jerajani**, an individual, having an address at MGM Medical College & Hospital, Sector 18, Kamothe, Navi Mumbai-410209, will serve as the principal investigator ("herein after referred to as Principal Investigator"),

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### Statutory Alert:

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

And

the institution at MGM Medical College & Hospital, located at Sector 18, Kamothe, Navi Mumbai-410209, ("herein after referred to as Institution")

(collectively, Principal Investigator and Institution, with its personnel, officers, board members, affiliates and agents, shall herein after be referred to as "SITE"),

And

BioQuest Solutions Pvt. Ltd, with a principal place of business at #24, Wellington St, Richmond Town, Bengaluru, Karnataka 560025. (herein after referred to as the CRO)

CRO, Site, and Principal Investigator are each individually referred to herein as a "Party" and collectively referred to herein as the "Parties."

### RECITALS

**WHEREAS**, by separate MSA dated \_\_\_\_\_, Dr. Reddy's Laboratories Limited (collectively, with its personnel, officers, board members, affiliates and agents, "SPONSOR"), with a principal place of business at 8-2-337, Road No. 3, Banjara Hills, Hyderabad, Telangana 500034, has engaged CRO, a contract research organization, acting as an independent contractor, to act on behalf of SPONSOR for the purposes of transferring certain obligations in connection to this Agreement, said obligations including negotiation and execution of the Agreement and payment administration of grant amounts in coordination with the SPONSOR and;

**WHEREAS**, CRO, acting as an independent contractor on behalf of SPONSOR, desires to coordinate an observational study entitled "**Real world, Non-interventional, Observational Study of Venusia® Max Cream as Moisturizer in Psoriasis**" ("the Study"), which shall be conducted according to SPONSOR's Protocol Number GGI-VENUSIA -11-16 ("Protocol") incorporated herein by this reference; and

**WHEREAS**, SPONSOR has developed an investigational product candidate designated as Venusia Max ("Investigational Product"); and

**WHEREAS**, SITE has acquired expertise in conducting research evaluations including observational studies; and

**WHEREAS**, SPONSOR and CRO wish to engage the SITE to facilitate and carry out the Study; and

**WHEREAS**, SITE has sufficient authority, competence and experience in conducting observational studies and, having reviewed the Protocol, and sufficient information regarding the Investigational Product related to the Study, desires to so participate in the Study as more particularly described in this Agreement; and

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**WHEREAS**, SITE is willing to undertake the Study for SPONSOR according to the terms, conditions and covenants hereinafter set forth.

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

#### ARTICLE 1

##### Statement of Work

1.1 SITE will take appropriate direction and supervision from CRO in connection with monitoring, supervision, and carrying out of the Study.

#### ARTICLE 2

##### Period of Performance

2.1 The performance of this Agreement shall be from the Effective Date till the date of termination of the Study by SPONSOR, unless earlier terminated in accordance with Article 12 of this Agreement.

#### ARTICLE 3

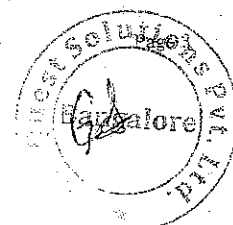
##### Conduct of the Study

3.1 The SITE agrees to conduct the Study in strict accordance with the Protocol attached to this Agreement as Attachment B, as amended from time to time, in accordance with the terms and conditions of this Agreement, and all applicable local laws and regulations applicable to the territory in which the Study is being conducted which is [mention the territory in which the Study is conducted] (herein after collectively referred to as, "Applicable Law").

3.2 The Study will be supervised by the Principal Investigator, who will personally be responsible for the direction of the research and the conduct of the Study in accordance with the applicable policies of the SITE, which the Principal Investigator and Institution represent and warrant are not inconsistent with (1) the terms of this Agreement, (2) the Protocol, (3) generally accepted standards of good clinical practice, and (4) Applicable Law. Principal Investigator shall conduct the Study and use his/her best efforts to complete the Study in a professional manner in accordance with the highest standards in the industry and in strict adherence to sub-parts (1) – (4) of this Article 3.2. If the Study is conducted by a team of individuals including Sub-investigator(s), the Principal Investigator shall be responsible for all Sub-investigators and Study team members utilized in any manner, in connection with the

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Study, and SITE shall instruct each Sub-investigator and team member to follow the direction of the Principal Investigator and otherwise adhere strictly to the Protocol.

3.3 SITE will notify CRO immediately if Principal Investigator is unable to continue as principal investigator for the Study. Institution further agrees that no other investigator may be substituted for the Principal Investigator without the prior written approval of CRO. If for any reason, Principal Investigator is unable to serve as principal investigator, and a successor acceptable to CRO/SPONSOR is not available, this Agreement shall be terminated as provided for in Article 12.2.

3.4 As required by Applicable Law, prior to initiation of the Study, SITE shall ensure that the Protocol has been reviewed and approved by the appropriate Ethics Committee ("EC") and shall provide CRO with evidence of such EC approval pertaining to the: (i) the Protocol and/or any subsequent modifications thereof, and (ii) the informed consent form and/or any subsequent modifications thereof.

3.5 As required by Applicable Law, SITE shall obtain the informed consent of patients to participate in the Study prior to said participation, and shall document the Study patients' informed consent by securing from each patient, his or her signature upon an informed consent form that complies with Applicable Law and is approved by an appropriate Ethics Committee ("EC"), a copy of which shall be retained by the SITE. The Study patient shall also receive a signed copy of the informed consent. Further, the name, medical history, and any and all information relating to a Study patient obtained as a result of or in connection with his or her participation in the Study shall be held in strictest confidence and trust, and shall not be disclosed or transferred to third parties except as expressly permitted by this Agreement or the Protocol.

3.6 SITE shall ensure that Study patients have agreed to participate in the Study as defined by the Protocol to be conducted at the Institution's facilities in compliance with Applicable Law.

3.7 SITE shall undertake to ensure that all Study patients are adequately informed of the aims, methods, anticipated benefits and potential hazards of the Study and the circumstances under which their personal data might be disclosed to relevant third parties including, but not limited to, CRO, SPONSOR and/or its affiliates, competent authorities, and/or ethics committees, in accordance with the requirements for such information as set forth in the Protocol prior to including any subject in the Study.

3.8 Institution and Principal Investigator hereby represents that neither: (a) has a conflict of interest that would affect the conduct of the Study; (b) has received any offer by SPONSOR, CRO and/or their respective representatives or affiliates, of any extra benefit for participation in the Study, including offers to family members. Further, SITE agrees to promptly notify CRO if it becomes aware of any conflict of interest that arises during the term of this Agreement. SITE not enter into any financial security transaction based on the Study data or the Study results. Without limiting the foregoing, SITE acknowledges that as of the date of this Agreement, neither Institution nor Principal Investigator are parties to any oral or written

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contract or understanding with any third party which (i) is inconsistent with this Agreement nor SITE's performance hereunder or (ii) will in any way limit or conflict with SITE's ability to fulfill its obligations under the terms of this Agreement. SITE further represents that it will not knowingly enter and will instruct its sub-investigators not to knowingly enter into any such conflicting agreements during the term of this Agreement

3.9 Adverse Events. SITE shall report to CRO and EC with a copy to SPONSOR, any death, life threatening, or serious adverse event, or other event as specified by the Protocol. Such notification shall be given promptly, and in no instance later than twenty-four (24) hours of becoming aware of such an event and shall be made in accordance with the procedures outlined in the Protocol concerning the reporting of adverse events.

3.10 No changes or revisions in the Protocol shall be made unless first mutually agreed upon in writing by SPONSOR and/or CRO and the SITE, and reviewed and approved by the EC in accordance with Applicable Law. If any changes in the Protocol affect the charge for research conducted in the Study, the SITE shall submit a written estimate of the charges for CRO's and SPONSOR'S prior written approval.

#### ARTICLE 4

##### Payment

4.1 In consideration of the work performed by SITE, payments shall be made to the SITE by CRO for evaluable Study patients in accordance with the terms of Attachments A; subject however, to the following terms and conditions:

4.1.1 In the event of early Study termination by SPONSOR, CRO, or the EC, as contemplated under Section 12 herein, the Institution will be reimbursed in full for completed Study patients except that Institution shall not be reimbursed in full or in part for any breach of this Agreement under Section 12. CRO shall reimburse Institution on a prorated basis for enrolled Study Subjects that are terminated early due to Sponsor, CRO, or EC termination of the Study. CRO will compensate Institution for services provided up to the effective date of termination and for any services provided after termination that are necessary to safeguard subject safety or comply with Applicable Law, rules, regulations or CRO requirements.

4.1.2 CRO reserves the right to temporarily withhold payment to Institution if it is determined from a monitoring visit or audit that there are significant errors in the Case record forms (CRFs) or where CRF's were not completed and/or provided to CRO in a timely manner.

#### ARTICLE 5

##### Record Keeping and Access

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5.1 Institution and Principal Investigator shall prepare, maintain and retain complete, current, organized, and legible Study documents relating to the performance of the Study which are required to be retained under Applicable Law and the Protocol (collectively, "Study Records") for each Study patient no later than ten (10) days after a visit. SITE shall respond to all data queries within seven (7) days from the date of such request. SITE will ensure that all personnel take appropriate measures to prevent unauthorized access to the electronic data capture system including maintaining confidentiality of their passwords.

5.2 Authorized representative(s) of CRO and SPONSOR, after arranging in advance with the Principal Investigator and the SITE, shall be allowed during regular business hours, and at reasonable intervals, to examine and inspect SITE facilities utilized in the performance of the Study, and to inspect and copy all Study data, records, and work products related to the Study, for purposes of assuring compliance with Applicable Laws, the Protocol, and the terms of this Agreement. Audits shall be at no additional cost to CRO/SPONSOR provided such audits are at mutually agreed intervals and do not significantly alter Institution's ability to meet any deadlines delineated in this Agreement.

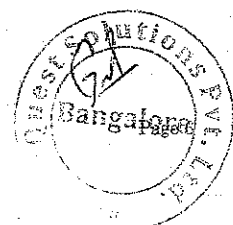
5.3 Subject to ownership of intellectual property under Article 8 and SITE's right to publish under Article 6, all results, data, reports, documents, information and the like generated in connection with the Study shall be the property of SPONSOR and shall be delivered promptly to SPONSOR. After the required retention period under applicable law for the Study, SPONSOR will have the option (i) to have the records returned to Sponsor, (ii) to have the records destroyed, or (iii) to continue having the documentation stored as set forth herein (at no additional cost).

#### 5.4 Regulatory Inspections and Audits.

A governmental or regulatory authority (including but not limited to representatives of the FDA or other international health agency or regulatory body, having similar regulatory authority over the subject matter of the Study) may, at reasonable times, examine and inspect the facilities being used to conduct the Study. In the event SITE is notified of any such regulatory inspection of SITE's records, facilities, equipment, or procedures, or other materials (including CRFs and patient medical records to the extent allowed by the informed consent document or other legal disclosure authorization), or request for access to the Principal Investigator and/or any sub-investigators to discuss the Study, SITE shall promptly notify CRO and shall provide CRO with copies of any reports issued by any such regulatory authority, and allow CRO to review and comment on any SITE response to such authority. If Institution is found deficient in any manner and reasonable efforts to correct the deficiency are ineffectual, CRO, in its sole discretion, shall either terminate SITE's continued participation in the Study and/or take such corrective actions as may be agreed between SPONSOR and CRO. It is further agreed that if Institution is notified that the Study is to be the subject of an audit, SITE shall promptly inform CRO and SPONSOR. If a formal response to any audit is required, Institution agrees to permit representatives of SPONSOR to review and comment on such response.

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## ARTICLE 6

### Publications

6.1 Neither Institution nor the Principal Investigator shall register the Study or Study results on any publicly accessible forum. Institution and Principal Investigator hereby acknowledge and agrees that the CRO/SPONSOR has the right to use the Study results in any manner deemed appropriate to CRO's/SPONSOR's business interests, both during, and following termination of this Agreement and/or the Study.

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

## ARTICLE 7

### Confidentiality and Use Restrictions

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

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

7.2 SITE shall return, retain or destroy all Confidential Information to CRO/SPONSOR at their request, at no additional cost, and under all circumstances except where retention of same is required by Applicable Law.

## ARTICLE 8

### Intellectual Property (IP)

8.1 For the purpose of this Agreement the term "Intellectual Property" or "IP" shall mean all patents, trademarks, designs (whether or not registered) and applications therefor, present and future copyright, trade secrets, rights in know-how and other rights of confidence and all other rights of a similar nature or having equivalent or similar effect to any of these which may subsist anywhere in the world. Intellectual Property that either party owned prior to execution of this Agreement, or develops independently of the Study (without the use of SPONSOR IP and/or Confidential Information), is that Party's separate property and is therefore, not affected by this Agreement. Neither party has any claims to, or rights in such intellectual property of the other party.

8.2 The Parties agree that the SPONSOR owns the proprietary rights (whether or not protectable by patent, copyright or other intellectual property rights) to the Study and/or Study data or materials and other reports required to be generated and submitted to the SPONSOR pursuant to the Protocol, and any data compiled therein, or any discovery, concept, or idea arising out of the Study, including but not limited to any/all Intellectual Property and Confidential Information provided to Institution and/or Principal Investigator relating to the Study, or any inventions, mechanisms, substances, works, trade secrets, know-how, methods, or techniques (including improvements), tangible research products, any intellectual property conceived and reduced to practice, made or developed, the Investigational Product, formulation of the Investigational Product, device, or biologic, including its administration or use, alone or in combination with any other drug or device and any related assay or biomarker, or any improvements or methods of using such Investigational Product, existing or pending patents and patent applications, records or compilations of information (excluding records/compilations set forth in Section 8.3 herein), Study data, including records produced by Institution and/or Investigator, innovations of any kind made in performance or carrying out of the Study, and the Protocol, and the like, either of which, in whole or in part, relating to the Study, derived from the use or access to SPONSOR's Confidential Information, or developed conceived or reduced to practice during the course of conducting the Study (collectively, "SPONSOR IP"). The Parties agree that title, interest and rights to any SPONSOR IP shall remain the sole property of the SPONSOR. The parties further agree that neither party will have any proprietary or other ownership rights in any such SPONSOR IP, but that such rights in and to the following will remain with SPONSOR, subject only to the right of Institution and Principal Investigator to use such information for: (i) Institution's own internal, non-commercial research and for

educational purposes provided such use does not violate SPONSOR's confidentiality rights or impede commercialization; and (ii) if required during the Study, for the provision of standard of care medical treatment for a Study patient, without jeopardizing the SPONSOR's Intellectual Property Rights on such subject matter. This Agreement shall not be deemed or construed to convey or transfer any of such intellectual property rights to SITE except insofar as necessary to permit SITE to conduct the Study which is the subject of this Agreement. SPONSOR and SITE acknowledge that the SPONSOR, owns the proprietary rights to the formulation of the Investigational Product, existing or pending patents and patent applications, trade secrets, know-how, and confidential information related to the Investigational Product and that these and all other proprietary rights shall remain the sole property of the SPONSOR.

8.3 Without SPONSOR's prior written approval, SITE will not knowingly use in the Study, any of its own or any third-party intellectual property that may interfere with SPONSOR's rights to any SPONSOR IP and/or Study Invention. Except as stated elsewhere in the Agreement, the Parties expressly authorize the use and grant a royalty-free license to their respective intellectual property to the other Party and to SPONSOR, to the extent necessary to accomplish the purposes of the Study.

8.4 The SITE will not transfer the Investigational Product or related information to any third party, or otherwise make the Investigational Product or related information available to any investigator other than those listed in the SPONSOR'S Protocol, nor to any clinic or medical facility for use with patients not properly enrolled in the investigational Study, and hereby acknowledges that the SITE shall not use or exploit the results of the Study for any purpose other than that contemplated by this Agreement.

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

## ARTICLE 9

### Use of Names

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

9.1.1. CRO/Sponsor may, without prior consent, identify Institution and Principal Investigator as the entity and/or persons conducting the Study;

9.1.2. CRO/SPONSOR may disclose the name of the Institution and the Principal Investigator to investors or potential investors or as required by local laws or security exchange regulations.

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

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

## ARTICLE 10

### Data Protection and Privacy

10.1 SITE shall undertake to ensure:

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

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

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

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

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

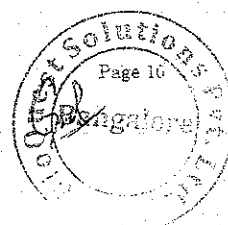
## ARTICLE 11

### Debarment

11.1 Principal Investigator and Institution hereby certify that they have not been debarred under (a) Applicable Law and (b) or excluded from participation in any government health care program. In the event that during the term of this Agreement, Principal Investigator or Institution (i) becomes debarred or excluded or (ii) receives notice of an action or threat of an

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action with respect to its debarment or exclusion, SITE shall notify SPONSOR and CRO immediately.

11.2 In the event that SITE becomes aware of the debarment/exclusion or threatened debarment/exclusion of any individual, corporation, partnership or association providing services to SITE which directly or indirectly relate to activities under this Agreement, SITE shall notify SPONSOR and CRO immediately. Upon the receipt of such notice by SPONSOR or CRO, or if SPONSOR or CRO otherwise becomes aware of such debarment/exclusion or threatened debarment/exclusion, the provisions of Section 12.2 shall apply.

## ARTICLE 12

### Termination

12.1 Performance under this Agreement may be terminated by SPONSOR or CRO for any reason or no reason upon thirty (30) days written notice to SITE. Performance may be terminated upon thirty (30) days prior written notice by the SITE if circumstances beyond its control preclude continuation of the Study. However, termination of this Agreement shall not relieve SITE of its obligations under Articles 5, 6, 7, 8 and 9 of this Agreement or any other obligation which is specifically expressed to survive expiry or termination. Other than in cases of termination for breach of this Agreement by SITE, CRO on behalf of SPONSOR shall make all payments due hereunder to SITE for actual costs, non-cancellable commitments incurred in the performance of the research, which have accrued up to the date of such termination, or, in case of a termination of this Agreement pursuant to Section 12.2 (f), up to the date of receipt of such final rejection. Should Institution have received higher payments than the payments due according to the work already performed, Institution shall reimburse the balance to CRO.

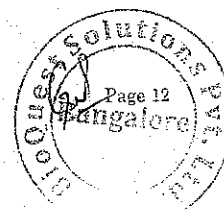
12.2 Performance under this Agreement may be terminated by SPONSOR or CRO immediately upon written notice without any further action or notice by either party, in the event (a) SITE ceases operations, is insolvent or unable to pay its debts when they become due; (b) of negligence or wilful misconduct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

12.4 Upon completion, termination (early or otherwise), suspension or discontinuation of the Study or upon the request of CRO, Institution and Principal Investigator will immediately cease Study activities and complete its normal Study completion responsibilities in an orderly and safe manner, of which shall include but is not limited to: (i) cooperate promptly and diligently in an orderly and safe manner, in the wind down of the Study, allowing SPONSOR and/or CRO access to records and facilities for Study close-out procedures, requiring Investigator to complete any actions required by the role of Investigator, and transferring to CRO all Study data and, if applicable, the administration and conduct of the Study; (ii) allowing Sponsor and/or CRO access to records and facilities for Study close-out procedures, and requiring Investigator to complete any actions required by the role of Investigator; and (iii) Immediately delivering to the CRO and/or SPONSOR, all Confidential Information, except for copies to be retained in order to comply with Institution's archiving obligations or for evidential purposes.

### Liability/Indemnification/Insurance

13.2 Institution. Institution shall be liable for, and agrees to indemnify and hold the CRO and Sponsor harmless from and against, any and all Losses caused by or attributable to Institution's (including Investigator), and/or any of its affiliates, subsidiaries, employees (including sub-investigators), officers, directors, contractors, sub-contractors, consultants or agents (collectively, "Representative(s)"): (i) negligent acts, omissions, wilful or intentional and/or professional malfeasance or misconduct of any Representative(s) involved in the Study; and (ii) breach of any of the terms of this Agreement or for violation of Applicable Law.

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### 13.3 Insurance

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

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

## ARTICLE 14

### Miscellaneous

#### 14.1 Assignment and Succession

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

#### 14.2 Independent Contractor Status

✓ In the performance of this Agreement the Principal Investigator and Institution shall be independent contractors with respect to CRO and SPONSOR. Neither Principal Investigator nor Institution is authorized to act as the agent for CRO or SPONSOR. CRO and SPONSOR shall not be bound by the acts of the Principal Investigator or Institution.

#### 14.3 Notices

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

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to INSTITUTION:

Institution Address:

MGM Medical College & Hospital  
Sector 18, Kamothe, Navi Mumbai-410209

Attention: Dr. Hemangi Jerajani

Telephone: 9820031483

To INSERT CRO NAME/ADDRESS:

BioQuest Solutions Pvt Ltd  
#24, Wellington street, Richmond town  
Bangalore - 560025

and to SPONSOR at:

Dr. Reddy's Laboratories, Limited  
8-2-337, Road No. 3, Banjara Hills  
Hyderabad, Telangana 500034 (INDIA)  
Fax: +914049002999

or to such other addresses as specified by the Parties in writing.

#### 14.4 Applicable Law

This Agreement shall be governed by the laws of India. Any proceeding arising out of or relating to this Agreement shall be brought in the courts located in Hyderabad. Each of the Parties irrevocably submits to the exclusive jurisdiction of such court in any such proceeding, waives any objection it may now or hereafter have to venue or to convenience of forum, agrees that all claims with respect to this Agreement shall be heard and determined on in such court, and agrees not to bring any claim arising out of or relating to this Agreement in any other court.

#### 14.5 Impossibility and Waiver

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

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#### 14.6 Force Majeure

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

#### 14.7 Conflict between Agreement and Protocol

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

#### 14.8 Third Party Beneficiaries

Notwithstanding any other provision in this Agreement to the contrary, the Parties agree that the SPONSOR is an intended third-party beneficiary of this Agreement and shall have the full right to enforce any and all obligations owed to it as through it were a party to the Agreement.

#### 14.9 Severability

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

#### 14.10 Integration and Amendment

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

#### 14.11 Warranties

Principal Investigator and Institution, for itself and its officers and directors, warrant and represent that they: (a) possess the necessary resources, skills, expertise and training to complete the Protocol professionally and competently; (b) are familiar with current laws and regulations related to the Study, and maintain a program for regularly updating their familiarity and compliance with such laws and regulations; (c) are licensed and in good standing with all necessary and appropriate government agencies; (d) have never been disciplined or debarred by any government agency; (e) have never been convicted of a

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felony; (f) are not currently the subject of any regulatory, civil or criminal investigation; and (g) shall maintain and provide evidence upon request comprehensive general liability insurance, professional liability insurance and worker's compensation insurance.

#### 14.13 Counterparts

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

#### 14.14 Headings

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

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

to INSTITUTION:

#### PRINCIPAL INVESTIGATOR

By: H.R. Jerajani

Printed Name: Dr. H.R. Jerajani

Title: Professor & HOD, Dept of Dermatology

Reg. No. MMC 37586

Professor and H.O.D.

Department of Skin and VD

MGM Medical College

INSTITUTION Kamothe, Navi Mumbai

By: [Signature] **Dean.**

Printed Name: Dr. G.S. Narshetti **M.G.M. Medical College & Hospital**  
**Kamothe, Navi Mumbai - 410209**

Title: Dean

BioQuest Solutions Pvt. Ltd

By: [Signature]

Printed Name: Gautam N. Sathia

Title: MD & CEO.