Certificate No.	:	IN-UP18074489488351X
Certificate Issued Date	:	24-Feb-2025 06:04 PM
Account Reference	:	NEWIMPACC (SV)/ up14046204/ GAUTAMBUDDH NAGAR 2/ UP-GBN
Unique Doc. Reference	:	SUBIN-UPUP14046204333615015187O9X
Purchased by	:	CLINICAL RESEARCH NETWORK INDIA PVT LTD
Description of Document	:	Article 19 Certificate or other Document
Property Description	:	Not Applicable
Consideration Price (Rs.)	:	
First Party	:	CLINICAL RESEARCH NETWORK INDIA PVT LTD
Second Party	:	DR RENU DHASMANA HIMS SRHU DEHRADUN
Stamp Duty Paid By	:	CLINICAL RESEARCH NETWORK INDIA PVT LTD
Stamp Duty Amount(Rs.)	:	500 (Five Hundred only)

Please write or type below this line

CLINICAL TRIAL AGREEMENT

This Clinical Trial Agreement (the "**Agreement**") is made on 25th Day of February, 2025 ("**Effective Date**") by and between

Clinical Research Network India Pvt Ltd, a company incorporated under the laws of India having its registered office at B-806,807, Advant Navis Business Park Plot #7, Noida-Greater Noida Expressway, Sector 142, Noida, Delhi-NCR, Uttar Pradesh 201305, India ("**CRO**"), of the First Part; and

Dr. Renu Dhasmana, a registered medical practitioner holding MCI registration number: **2325** currently serving as HOD Ophthalmology and Vice Principal (Postgraduate) at Himalayan Institute of Medical Sciences, Swami Rama Nagar, Doiwala, Dehradun 248140, Uttarakhand, India, hereinafter referred to as ("**Principal Investigator**"), of the Second Part; and

Swami Rama Himalayan University, a University established under section 2(f) of the UGC Act and enacted vide Uttarakhand State Act **(For its constituent academic unit *Himalayan Institute of Medical Sciences*)** having its registered office at Swami Rama Nagar, Jolly Grant,

Dr. Renu Dhasmana
Professor & Head
Department of Ophthalmology
HIMS, Dehradun

Doiwala, Dehradun, Uttarakhand 248016, represented by Registrar **Commander ChallaVenkateswar** hereinafter referred to as**("Institution/Site")**of the Third Part; and

KV Clinical Research Pvt Ltd, having Registered address at Off. No. 616,617 Sixth Floor Golden Trade Centre New Rajendra Nagar Raipur-492001 (C.G), hereinafter referred to as ("**SMO**") of the Fourth Part.

CRO, Principal Investigator, Institution and SMO are collectively referred to as**"Parties"**.

WHEREAS,

The CRO is a Contract Research Organization is engaged in the business of undertaking clinical trials (Phase I-IV), data management, biostatistics, medical writer, regulatory consulting, and other research work for the pharmaceutical industry. The CRO has been outsourced by **Gennova Biopharmaceuticals Limited ("Sponsor")** to conduct the clinical trial/study. The CRO is authorized by the Sponsor to enter into the agreement on its behalf and has undertaken to abide by all the terms and condition of this agreement. Authority letter is attached as annexure with this agreement.

A. The Institution has its own premises fully equipped to conduct the Study mentioned under this Agreement;

B. The CRO has already identified the Principal Investigator based on her experience and expertise and also furnished sufficient information regarding the Study drug and the Protocol;

C. The Principal Investigator has, after careful review of the Protocol and other materials relating to the Clinical Trial conveyed her willingness to the CRO to conduct the proposed Study;

D. The CRO shall provide technical and financial support mentioned in this Agreement to the Principal Investigator to conduct the Clinical Trial and the Principal Investigator in lieu of such support has agreed to enter into this Agreement with the CRO; and

NOTARY R. Inder Singh Negi Advocate Dehradun District (Reg. No. 19/01/2002) UTTARAKHAND (INDIA)

NOW, THEREFORE, the Parties hereto, in consideration of the mutual covenants and premises contained herein, enter into this Agreement and agree as follows:

Swami Rama Himalayan University Registrar

1. Definitions

Dr. Renu Dhasmana Professor & Head Department of Ophthalmology SRMS, Dehradun

KV CLINICAL RESEARCH PVT LTD

Clinical Research Network India Private Limited

1.1. "**Study**" or "**Clinical Trial**" shall mean study entitled: A Phase III **P**rospective, **R**andomized, **O**pen-labelled, Blinded endpoint (PROBE), **M**ulti-centric, Parallel Group, Non-**i**nferiority **S**tudy to compare the **E**fficacy and **S**afety of GBL1204 with Ranibizumab in Patients with Wet Age-Related Macular Degeneration **(PROMISES Study).**

1.2. **"Sponsor"** shall mean an individual, company, institution, or organization that takes responsibility for the initiation, management, and/or financing of a clinical study or trial at study site. Sponsor shall be the owner of the Clinical Trial Protocol and is interested in carrying out the said Clinical Trial, through the CRO, SMO & PRINCIPAL INVESTIGATOR at study site.

1.3. "**Protocol**" shall mean the description of the Study contained in the Study protocol number: **GBL1204/2024/01** and all amendments thereto as the Parties may from time to time agree in writing.

1.4. "**Study drug**" or "**Investigational Drug**" shall mean

- Test Product: GBL1204 (Bevacizumab manufactured by Sponsor as ophthalmic grade).

- Comparator Product: Ranibizumab (Accentrix®, Novartis India Limited, India)

1.5. "**Ethics Committee**" shall mean an independent body, including but not limited to, independent ethics committee or institutional review board, constituted and registered with the licensing authority under the provisions of New Drugs and Clinical Trial Rules- 2019 and rules amended thereof.

1.6. **"**Adverse **event"** means any untoward medical occurrence (including a symptom or disease or an abnormal laboratory finding) during treatment with an investigational drug or a pharmaceutical product in a patient or a trial subject that does not necessarily have a relationship with the treatment being given.

1.7. **Serious Adverse Event (SAE):-** Any untoward medical occurrence that, at any dose:

- results in death
- is life-threatening
- requires inpatient hospitalization* or prolongation of existing hospitalization
- results in persistent or significant disability/incapacity
- is a congenital anomaly/birth defect
- is medically significant or requires intervention to prevent one of the outcomes listed above

1.8. **"Publication"** means a paper, article, manuscript, report, poster, Internet posting, presentation slides, abstract, outline, video, instructional material, presentation (in the

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Department of Ophthalmology
HIMS, Dehradun

form of a written summary), or other disclosure of Registry Results, in printed, electronic, oral or other form.

1.9. **"Results"** shall mean and include all the methods, data, analysis and conclusions of a Registry.

1.10. **"Contract Research Organization or Clinical Research Organization (CRO)"** is a service organization that provides support to the pharmaceutical and biotechnology industries in the form of outsourced pharmaceutical research services (for both drugs and medical devices).

1.11. **"Site Management Organization (SMO)"** is a company that provides clinical trial management services to pharmaceutical, biotech, medical companies or Medical Institutions. SMOs help sponsors streamline their administrative processes while ensuring that all regulatory requirements are met. They also support Clinical Research Organisation (CRO) and clinical investigators at the site with startup, monitoring, and closeout responsibilities.

1.12. **"Study Site"** means and include Swami Rama Himalayan University (SRHU), Jolly Grant, Dehradun.

2. Responsibility of the Principal Investigator and the Institution/Site

2.1. The Institution agrees to provide full support to the Principal Investigator to conduct the Clinical Trial in its premises and utilize reasonably the facilities available in the Institution for the Study and shall allot qualified co-investigators, investigators and other persons with prior consent of the CRO, for proper conduct of the Study in accordance with the terms of this Agreement and the Protocol.

2.2. The Principal Investigator and SMO shall be jointly and severally shall be responsible (a) to conduct and complete the Clinical Trial of the CRO strictly in accordance with the applicable regulatory requirements and the Protocol as approved by the Ethics Committee; (b) to comply with all applicable rules, regulations and guidelines, both national and international, including but not limited to, ICH Good Clinical Practice, Good Clinical Practice Guidelines issued by CDSCO, Directorate General of Health Services, Govt. of India; New Drugs and Clinical Trials Rules-2019, notifications made thereunder (as amended from time to time), ethical principles contained in the current revision of Declaration of Helsinki, Ethical Guidelines for Biomedical Research on Human Subjects issued by the Indian Council of Medical Research ("Applicable Laws&Guidelines"); (c) to fulfill all other terms and conditions stipulated herein and in the Annexures hereto, during the period of, and also after the completion of, the Clinical Trial as agreed upon by him; and (d) to provide CRO a copy of registration certificate issued by the licensing authority to Ethics Committee before initiation of the Clinical Trial.

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Professor & Head
Department of Ophthalmology

Registrar
Swami Rama Himalayan University

2.3. The SMO will provide all administrative support to Principal Investigator to conduct the study as per the study protocol.

2.4. The Principal Investigator along with any co-investigator employed in the Institution shall personally review all case report forms to assure its completeness and accuracy. A case report form is deemed complete when:

(i) The case report form has been completed by the Principal Investigator/designee in accordance with Study requirements.
(ii) it relates to a properly qualified subject who participated in and completed the Study in accordance with all Study requirements and directions from the CRO; and
(iii) It can be used in all analyses of the Study results.

The Principal Investigator undertakes that all data shall be submitted in a timely manner to the CRO.

2.5. Principal Investigator shall at all-time exercise independent medical judgment as to the compatibility of each subject with the Study as per Protocol requirements. Principal Investigator shall notify the CRO, Chairman of Ethics Committee, the Institution and licensing authority within twenty-four (24) hours of any serious adverse events related to or unrelated to the Study Drugs and of overdoses and any other event as set forth in detail in the Protocol.

2.6. The Principal Investigator and CRO shall provide report of serious adverse events of death after due analysis to the Chairman of the Ethics Committee, IEC and Chairman of the expert committee constituted by licensing authority with a copy to the licensing authority and to the Institution of any deviations in the Protocol or serious adverse events immediately and in any event within fourteen (14) calendar days from the date of occurrence of such deviation and/or serious adverse events of death, as the case may be.

2.7. The Principal Investigator and CRO shall provide report of serious adverse events other than death after due analysis to the Chairman of Ethics Committee, licensing authority and to the Institution within fourteen (14) calendar days of occurrence of such serious adverse events other than death.

2.8. In the event the Principal Investigator becomes unwilling or no longer in the employment of the Institution or unable to perform the Study, at any later stage, the Principal Investigator shall provide notice to the Study subjects, the institution, Ethics Committee and CRO at least thirty (30) days before Principal Investigator intends to stop Clinical Trial. The Principal Investigator and Institution shall endeavor to promptly recommend a replacement Principal Investigator from among the

NOTARY Ravinder Singh Negi Advocate Dehradun District Reg. No. 19(01)2002 GOVT. OF UTTARAKHAND (INDIA)

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Swami Rama Himalayan University Registrar

consultants of the Institution. The CRO shall have the exclusive right to approve or reject any such replacement of Principal Investigator. The new principal investigator which is approved by the CRO shall be required to agree to the terms and conditions of this Agreement. In the event CRO does not approve such new principal investigator, the Study will be terminated immediately, and no further payment shall be made to Principal Investigator and Institution. Upon such termination, Institution shall (i) ensure appropriate therapy and follow-up for enrolled Study subjects; and (ii) maintain all Study related documents for such time as may be required by CRO and shall take measures to prevent accidental or premature destruction of these documents.

3. Conduct of Clinical Trial

3.1. The CRO shall appoint project manager(s)to monitor the Clinical Trial and also reserves its right to nominate any other persons as monitor.

3.2. No payment shall be made by CRO to the Principal Investigator for the visit, if the Study subject is not participating in that particular visit.

3.3. Principal Investigator agrees that if Principal Investigator cannot conduct and complete the Study to the satisfaction of the CRO within the time prescribed by the CRO, the CRO may at its sole discretion and without prejudice to its rights under this Agreement, send a notice to the Principal Investigator to discontinue the Study. The Principal Investigator to cease recruiting subjects for the Study immediately upon receiving such notice from the CRO to stop recruiting the subjects for the Clinical Trial.

3.4. Principal Investigator shall ensure that the informed consent form signed by or on behalf of the Study subjects have been reviewed and approved by Ethics Committee prior to initiation of the Study. Upon approval of the informed consent form by the Ethics Committee, a copy of the approval letter shall be provided to the CRO by the Principal Investigator, who shall further obtain informed consent form duly signed by each of the subjects or on behalf of the Study subjects enrolled in the Study in accordance with Applicable Laws and Guidelines. The Principal Investigator shall ensure to maintain for record an audio – video recording of the informed consent process of individual subjects, if applicable, including procedure of providing information to the subjects and their understanding on such consent. However, at the request of the CRO, PrincipalInvestigator shall handover a copy of such recording for regulatory compliance or any order.

NOTARY Rajender Singh Negi Advocate Dehradun (Uttarakhand) Reg. No. 19/01/2002 GOVT. OF UTTARAKHAND (INDIA)

3.5. The Study is being entrusted to the Principal Investigator directly by the CRO as a technical assignment, based on the skill, knowledge and experience of the Principal Investigator in the specialty areas related to the Clinical Trial and Institution's experience as a qualified testing facility in the Clinical Trial. The Principal Investigator shall be personally obligated to conduct and complete the Clinical Trial in accordance

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with the Protocol as well as other terms and conditions specified by the CRO herein. All items received from the CRO/Sponsor, from time to time, (including, but not limited to, Study Drug, documents, Confidential Information, communications, instructions etc.), records and registers required to be maintained and all data generated hereunder by the Principal Investigator, shall be under the exclusive care, custody and responsibility of the Principal Investigator throughout the period of the Clinical Trial and thereafter for a period of five (5) years after the CRO has discontinued/completed its Study or such longer period as required by Applicable Laws & Guidelines. At the end of such period mentioned above, the Institution shall obtain written approval from CRO before destruction of such data.

CRO/Principal Investigator/SMO agrees to assume all the legal obligations ~~of the CRO~~ for the Study related duties and functions under this Agreement and the Protocol.

3.6. Principal Investigators hall ensure that all the individuals involved in the conduct of the Study shall strictly adhere to the terms and conditions of this Agreement. Principal Investigator represents and warrants that it shall not use in any capacity, in connection with the Study, any individual who is not duly qualified or has been debarred pursuant to any Applicable Laws & Guidelines or against whom any action, suit, claim, investigation or legal or administrative proceeding is pending. Principal Investigator represents and warrants that no action, suit, claim investigation or legal or administrative proceeding is pending or threatened relating to Principal Investigator's debarment and/or debarment of the persons engaged by Principal Investigator to assist for the Study.

3.7. Principal Investigator/SMO represents and warrants that he has obtained and shall maintain in full force and effect all the necessary approvals, permissions and sanctions from the Institution & Ethics Committee.

4. Study Drug

4.1. The Sponsor/Sponsor's representative will provide the Study Drug to the Principal Investigator free of cost/charge and in such quantities sufficient to complete the Study, together with guidelines and descriptions for the safe and proper use, administration, storage and disposal of the Study Drug. Principal Investigator shall use Study Drug and other items only to conduct the Study in accordance with the Protocol and Applicable Laws & Guidelines and instructions of the CRO and shall not chemically, physically or otherwise modify the Study Drug, unless specifically required to do so by the CRO in writing to the Principal Investigator. Principal Investigator agrees that they shall administer, handle, use, store (at institute), and or dispose the Study Drug and other items provided by the CRO in compliance with CRO's instructions and all Applicable Laws & Guidelines.

Dr. Renu Dhasmana
Professor & Head
Department of Physiology
HIMS, Dehradun

4.2. The Parties hereby clearly understand that the subject matter of the Agreement is to clinically evaluate the efficacy and safety of the Study Drug and that the Clinical Trial shall not constitute complete treatment to cure any disease.

5. Visit and Inspection

5.1. The CRO/Sponsor or its authorized representatives, and regulatory authorities to the extent permitted by law, shall have the absolute right to:

i. Examine and inspect the Institution's facilities whenever Principal Investigator is conducting Study.
ii. inspect and copy all data and work products relating to the Study, and
iii. Audit all reports and data from Principal Investigator to ensure compliance with the terms of this Agreement and Protocol.

6. Payment

6.1. Institution, SMO and Principal Investigator hereby undertakes that in consideration of Principal Investigator's carrying out Clinical Trial at the Institution in accordance with the terms of this Agreement, CRO shall make the payment as per the payment schedule as set forth in **Exhibit A**.

6.2. The Parties agree that the payment of the amount set forth in Exhibit A will be paid by the CRO to compensate all the expenses incurred in execution and conducting the Clinical Trial at the Institution so that, neither the Study subject, nor the insurance program nor the public assistance agency shall be liable for the same. The payment of the amount set forth in Exhibit A is also meant to compensate Principal Investigator for the professional and clerical allowances for all the activities as per the Protocol including but not limited to, preparation of the subject records, medication accountability records and other trial related documentation.

6.3. Institution, SMO and Principal Investigator shall not be entitled to any other expenses, benefits, consideration or fee of co-investigator, whether monetary or otherwise under this Agreement or elsewhere and it covers all out of pocket expenses incurred by Principal Investigator in conducting Study at the Institution including but not limited to telephone, telex, travel and office expenses.

6.4. CRO shall be entitled to deduct tax at source (if applicable) while making payment under this Agreement.

7. Insurance

NOTARY Rajender Singh Negi Advocate Dehradun (Uttarakhand) Reg.No.1(01)2002 GOVT. OF UTTARAKHAND (INDIA)

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The CRO and Sponsor either jointly or severally undertakes that it will secure and maintain in full force and effect throughout the performance of the Study (and following termination or early termination of the Study and to cover any claims arising from the Study) a clinical trial liability insurance policy from an Indian insurance company for an amount appropriate to, and in accordance with, the CRO's activities and obligations contemplated in this Agreement.

8. Publication of Results

It is the general policy of the Sponsor to encourage publication of results of Clinical Trial on a case-to-case basis. However, according to good scientific practice no interim data should be published by the Principal Investigator/ Institution unless agreed by the Parties in writing. It is further agreed that when the Principal Investigator/ Institution request for publications, the manuscript shall be based on final report of the Study and before any publication it shall be sent to the Sponsor for its perusal, comments and approval. The Sponsor may at its discretion may either refuse the publication or forward it to the Principal Investigator/ Institution along with its comments or modifications which shall be final and binding on the Principal Investigator/ Institution.

9. Publicity and Product Promoting Activity

It is agreed that no party shall issue any press release or other third party communication relating to this Agreement without the prior written consent of the other Party except to the extent that the Sponsor shall have absolute right to issue any press release relating to the Study related data. Principal Investigator shall not use the name of the CRO/Sponsor and/or its employees in any advertising or sales promotional material or in any other way not required by law or regulation without the prior written consent of the CRO/Sponsor.

10. Confidentiality

10.1 During the term of this Study Agreement, for a period of Five (05) years & after termination of this Study, neither party shall disclose or use for any purpose other than performance of the Study, any information including, but not limited to, any and all trade secrets, know-how, privileged records or other confidential or proprietary information and data both technical and non-technical (except as required under law disclosure to any governmental authority or any other person under the provisions of any applicable law, and also disclosure to their professional advisors/auditors and the like), disclosed by either Party to the other ("Confidential Information"). Confidential Information shall be in writing, clearly marked "Confidential Information" and sent by the either party directly to the Principal Investigator for this Study.

10.2 The parties shall hold in confidence the identity of any Subject and shall comply with all applicable law(s) regarding the confidentiality of such Subject's records.

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Professor & Head
Department of Ophthalmology
HIMS, Dehradun

10.3 Each party shall promptly return to the other party any Confidential Information no longer needed for the purposes of this agreement or if so requested by the other party.

10.4 The Principal Investigator and the Institution agree to keep confidential all materials, documents and confidential information that the CRO/Sponsor discloses to the Principal Investigator and the Institution pursuant to this Agreement and also all materials, documents and information's gathered, generated or developed by Principal Investigator and the Institution under the Study including but without limitation to results and discoveries emanated from the Study, regardless of whether such information is marked as "Confidential," "Proprietary" or the like, which is furnished to the Principal Investigator by or on behalf of the CRO/sponsor whether in written, electronic, oral, visual or other form ("Confidential Information").

10.5 The Principal Investigator and the Institution agree, represent and warrant that any Confidential Information that they receive shall be protected at least, with the same degree of care and protection in the strictest confidence as of its own and shall take all reasonable measures to protect it. The Principal Investigator and the Institution shall use such Confidential Information only for the purpose of fulfilling their obligations mentioned herein and shall not disclose such Confidential Information without the prior written consent of the CRO/Sponsor to any third party except as required by law provided that the Principal Investigator and the Institution shall:

(i) first give prompt notice of such disclosure requirement to the CROso as to seek any limitations on or exemptions from such disclosure requirement; and

(ii) reasonably co-operate the CRO/Sponsor in any such efforts of defense to be made before appropriate authority.

10.6 All clinical data, including case report forms and other information and discoveries resulting from the Study ("Inventions") shall be the sole property of the Sponsor and will be treated as "Confidential Information" by the Principal Investigator and the Institution and may not be used by the CROin any manner without the express consent of the Sponsor. Further, Principal Investigator and the Institution shall assign to the Sponsor all of their rights, title, and interest in such Inventions.

10.7 All Confidential Information disclosed pursuant to this Agreement, together with all copies thereof, summaries and all information, know-how, data and materials generated by the use of the Confidential Information, shall be returned to the CRO by Principal Investigator and the Institution forthwith upon written request or upon termination of this Agreement, whichever is earlier.

10.8 The Principal Investigator, Institution, and CRO acknowledge that Confidential Information (as defined in this Agreement) is of a special and unique nature and that its protection is critical to both Parties. Each Party agrees to maintain the confidentiality of the Confidential Information and only use it as required to fulfill their obligations under this Agreement. In the event of any kind of breach of confidentiality by either Party, including the Principal Investigator, Institution, or any co-investigator, or any party in receipt of Confidential Information under this Agreement, both Parties agree that the affected Party shall be entitled to seek appropriate remedies, including injunctive relief or specific performance, from a

NOTARY Rajinder Singh Negi Advocate Dehradun District Uttarakhand GOVT. OF UTTARAKHAND INDIA

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court of competent jurisdiction. However, neither Party shall be entitled to seek such relief without demonstrating actual and specific harm resulting from the breach. In such cases, the Parties agree that any equitable relief (such as injunctive relief or specific performance) will be granted only where it is necessary to prevent irreparable harm, and where damages or other remedies at law are insufficient.

If a Party is found by a court of competent jurisdiction to have breached this Agreement, the breaching Party shall reimburse the non-breaching Party for reasonable costs and expenses incurred in connection with the litigation, including reasonable attorney's fees and other legal expenses. This provision shall apply equally to both Parties, regardless of which Party is found to be in breach. In no event shall either Party be liable for indirect, consequential, or punitive damages arising out of a breach of this Agreement, except in cases of wilful misconduct or gross negligence.

10.8 Intellectual Property:

It is expressly agreed that the institution retain all right, title, and interest in and to pre existing IP, including patents, copyrights, trademarks, trade secret, methodologies and property technologies that are owned or controlled by institution prior to commencement of clinical trial.

11. Duty To Update Regarding Safety Information:

CRO shall notify Investigator in writing of any subject safety issues that may arise during the course of the Study and, thereafter, in accordance with concerned authorities requirements. In addition, if CRO becomes aware of any findings through its site monitoring process that may possibly affect the safety or welfare of subjects enrolled in the Study, CRO will notify the Institution/investigator through the Institution's authorized representative.

12. Force Majeure:

Any delay or failure of a party hereto to perform its obligations hereunder will be excused if and to the extent that it was caused by an event or occurrence beyond such party's reasonable control and without its fault or negligence ("force majeure"). Force majeure includes, but is not limited to, acts of God, actions by any government authority, fires, floods, windstorms, explosions, riots natural disasters, wars, sabotage or acts of terrorism, pandemic. A party claiming Force Majeure must provide the other party with written notice of such delay (including the anticipated duration of the delay) within ten (10) days of the occurrence of Force Majeure. If the delay lasts more than ninety (90) days, either Party may terminate this Agreement upon written notice. Regardless of whether this Agreement is terminated or naturally expires, Sponsor/CRO shall be responsible for payment for all services or procedures actually performed in compliance with the study protocol and all non-cancellable Institution expenses incurred or obligated prior to termination or expiration and shall remit such total within thirty (30) days of Institution's written request for final payment. In the event of any overpayment by Sponsor/CRO, Institution shall refund such overpayment to Sponsor/CRO.

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13. Relationship Of The Parties:

The relationship of CRO to institution and investigator shall be that of an independent entity and none of the parties shall hold itself out to third parties as purporting to act as, or on behalf of, the other party hereto.

14. Compensation for Adverse/ Serious Adverse Event:

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The Sponsor or its representatives acknowledges and agrees that in any Adverse and Serious Adverse Event of a study participant arising from the Clinical Trial shall be compensated in accordance with the provisions of New Drugs and Clinical Trials Rules, 2019 or any other Law enforce.

15. Use of other Parties Name:

Neither the CRO nor the institution shall use directly or by implication the names of the other party, nor any of the other party's affiliates or contractors, nor any abbreviations thereof, or of any staff member, faculty member, student, or employee of the other party in connection with any products, publicity, promotion, financing, advertising, or other public disclosure without the prior written permission of the other party.

16. Notices:

That any notice, consent, waiver and/or other communication pursuant to this agreement must be in writing signed by the person serving it, or by a person duly authorized by the person serving it, and will be deemed to have been duly given when (a) delivered by hand (with written confirmation of receipt); or (b) when received by the addressee, if sent by a recognized overnight delivery service (receipt requested), in each case to the designated persons and the appropriate addresses mentioned at the end of this agreement.

17. Representation And Warranties:

a. Each Party represents to the other that it has the necessary right and authority to enter into this Agreement and to the best of its knowledge, it is not party to any agreement which would prevent it from fulfilling its obligations under this Agreement.
b. The CRO warrants to the Institution that it shall obtain and maintain, throughout the term of this Agreement, all appropriate and applicable licenses, approvals, permits, certifications, and any other necessary authorizations required to lawfully perform the clinical trial and its obligations under this Agreement.

18. Amendments:

This Agreement may only be amended by the mutual written consent of all the parties.

19. Indemnification:

Each Party ("**Indemnifying Party**") agrees and undertakes to indemnify, hold harmless and defend the other Party ("**Indemnified Party**") from and against any and all **Losses** arising as a result of or arising directly out of (a) breach by the Indemnifying Party of any provision of this Agreement or (b) the Indemnifying Party's negligence

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HIMS, Dehradun

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Registrar

or willful default in relation to performance or non-performance of any of its obligations under this Agreement.

19.2. CRO/Sponsor shall indemnify, defend and hold harmless the Institution, Investigator, and/or other affiliated and cooperating hospitals and institutions, as well as the directors, officers, agents, employees, students, the members of their Institutional Review Boards, and others holding appointments within those institutions and their respective heirs, successors, and assigns (collectively "Institution Indemnities"), from any liability, loss, or damage they may suffer as a result of claims or judgments that arise from the Institution Indemnities' participation in and/or performance of the subject Study.

20. Severability & Waiver and Assignment

20.1 The invalidity or unenforceability of any term or provision of this Agreement, Agreement, shall not affect the validity or enforceability of any other term or provision of this agreement.

20.2 Waiver by anyParty or the failure byany Party to claim a breach of any provision of this Agreement shall not be deemed to constitute a waiver or estoppels with respect to any subsequent breach of any provision hereof.

20.3 This Agreement shall not be assigned as a whole or in part by Principal Investigator and/or Institution without the prior written consent of the CRO.

21 Validity & Termination

21.1 The term of this Agreement shall commence from theEffective Date set forth above and shall be valid for a period of 3 (three) years unless earlier terminated, amended or extended in accordance with the terms and conditionsor until this Agreement is terminated due to:-

a. Determination by the CRO/Sponsor that the Principal Investigator is not performing the Study as required in the Protocol and/ or is not meeting the agreed upon enrollment;

b. Failure of the Principal Investigator's or its associated staff or any other person engaged in the Study (excluding subjects) to be available, upon reasonable prior notice by the CRO, to meet at mutually convenient time with the CROenabling it to monitor the course of the Study as necessary and to discuss information relevant to the Study;

c. Determination by the CRO that business or scientific considerations require termination;

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Clinical Research Network India Private Limited

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d. At the request of either DCGI or Ethics Committee;
e. Notification to the CRO/Sponsor from central or state regulatory authorities to terminate the Study;
f. Failure of the Principal Investigator/ Institution to provide access by the CRO's representatives all original medical records necessary to verify entries on the Study case report forms;

21.2 The CRO, Principal Investigator or Institution may terminate this Agreement:

a) At any time upon thirty (30) days written notice to other party.
b) Immediately for safety reasons relating to the use of the Study Drug.
c) By notice in writing to the other Parties if the other Parties commit a breach of this Agreement, and which, in the case of a breach capable of remedy, shall not have been remedied by the defaulting Party within thirty (30) days of receipt of notice identifying the breach and requiring its remedy.

22 Effect of Termination

22.1 Upon receipt of notice of termination, the Principal Investigator shall immediately stop enrolling subjects into the Study and to the extent medically permissible, cease administering the study drug and conducting clinical trial on subjects already entered into the study. The Principal Investigator shall request all Study subjects within one month from the date of termination notice to attend a follow up visit for proper safety assessment of the subjects enrolled. The Principal Investigator shall use all reasonable efforts to complete reports for all subjects that have been entered into the Study prior to the date of termination of this Agreement.

22.2 Upon termination or completion of the Study, the Principal Investigator and Institution shall return to the Sponsor all unused Study drugs, whether completed or not and other related materials including but not limited to materials that were furnished to the Principal Investigator/Institution by or on behalf of the CRO. In case, the CRO/Sponsor desires destruction of aforementioned material, the Principal Investigator/Institution shall destroy such material in front of authorized representative of the CRO and shall also provide the CRO with a certificate of destruction.

22.3 Upon the completion of any ongoing study, each party shall fulfill any remaining obligations under this Agreement, including but not limited to the submission of reports, data, or other deliverables related to the study.

22.4 The CRO is liable to pay as per Exhibit A in respect of all subjects that have been entered into the study prior to the date of termination of this agreement and also towards follow-up therapy expenses to these subjects, as per study protocol.

23 Miscellaneous

Dr. Renu Dhasmana
Professor & Head
Department of Ophthalmology
HIMS, Dehradun

Registrar

23.1 It is agreed by the Parties that the Principal Investigator and Institution shall act in the capacity of independent contractor hereunder and not as employees, agents or joint ventures of or with CRO. Neither Principal Investigator nor Institution shall have any authority to represent or bind the CRO.

23.2 Principal Investigator shall comply with all the terms of the investigator undertaking he/she has provided to the CRO.

23.3 This Agreement contains the entire understanding of the Parties hereto and supersedes all prior oral and written agreements and understandings of the Parties except confidentiality agreement, if any, pertaining to the subject matter hereof.

23.4 If the terms contained in any of the Exhibit attached hereto conflict with any provisions contained in this Agreement, the terms contained in this Agreement shall prevail. Unless otherwise provided herein, this Agreement may not be amended, supplemented or otherwise modified except by an instrument in writing signed by the Parties hereto.

23.5 The Parties undertake to notify each other of all events that influence the performance of this Agreement.

24 GOVERNING LAWS AND DISPUTES RESOLUTION

24.1 This Agreement shall be governed by and construed in accordance with the laws of India.

24.2 That any dispute and/or difference arising out of or relating to this Agreement, including interpretation of its terms shall be resolved amicably through joint discussion by the authorized representatives of both the parties.

24.3 That in case dispute is not resolved through joint discussion, same shall be finally settled through arbitration by a sole arbitrator mutually appointed by the Parties, as per the provisions of the Arbitration and Conciliation Act, 1996, as amended from time to time. In the circumstance that parties fail to appoint a sole arbitrator then the Parties shall appoint one arbitrator each who shall in turn jointly appoint the third arbitrator. The arbitration proceedings shall be conducted in English language and behind Dehradun, Uttarakhand, India.

24.4 The award of the arbitrator shall be final and binding on the Parties. However, the final jurisdiction shall lie with the courts of Dehradun, Uttarakhand, India.

24.5 Each of the Parties hereby expressly submits to the jurisdiction of the courts of Dehradun, Uttarakhand, India.

NOTARY Govt. of Uttarakhand India — Advocate, Dehradun District

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Department of Ophthalmology
HIMS, Dehradun

KVR Clinical Research Pvt. Ltd.

Swami Rama Himalayan University — Registrar

Clinical Research Network India Private Limited

IN WITNESS WHEREOF, the Parties hereto have caused this Agreement to be duly executed as of the date first set forth above in triplicate each being legally authentic and binding.

For Clinical Research Network India	For Principal Investigator	For Institute/Site	For SMO
Signature:	Signature:	Signature:	Signature: .....
Name: Mr. Yogesh Saini	Name: Dr. Renu Dhasmana	Name: Commander Challa Venkateswar (Retd.)	Name: Dr. Kirti Patel
Title: Assistant Director	Title: HOD & Vice Principal	Title: Registrar	Title: COO
Address: B-806,807, Advant Navis Business Park Plot #7, Noida-Greater Noida Expressway, Sector 142, Noida, Delhi-NCR, Uttar Pradesh 201305, India	Address: Department of Ophthalmology, Himalayan Institute of Medical Sciences, Swami Rama Nagar, Doiwala, Dehradun 248140, Uttarakhand, India	Address: Himalayan Institute of Medical Sciences, Swami Rama Nagar, Doiwala, Dehradun 248140, Uttarakhand, India	Address: Office No 616, 6th Floor, Golden Trade Center, New Rajendra Nagar, Raipur, Chhattisgarh 492001

NOTARY Rajender Singh Negi Advocate Dehradun District Reg.No.19(01)2002 GOVT. OF UTTARAKHAND (INDIA)

ATTESTED
RAJENDER SINGH NEGI
Advocate & NOTARY
Chamber No.92, 1st Floor
Opposite Bar Office, Dehradun

Dr. Renu Dhasmana
Professor & Head
Department of Ophthalmology
HIMS, Dehradun

Exhibit A
Financial Details

Details of the payment to be made for completing of following visit specific activities of each study subject:

Sr. No.	Particulars	Fee/Charges for Visit 1	Fee/Charges for Visit 2	Fee/Charges for Visit 3	Fee/Charges for Visit 4	Fee/Charges for Visit 5	Fee/Charges for Visit 6	Total
1.	Principal Investigator	15000	15000	15000	15000	15000	15000	90000
2.	Co-I	5000	5000	5000	5000	5000	5000	30000
3.	Institutional Overhead 20%	4000	4000	4000	4000	4000	4000	24000
4.	CRC fees	4000	4000	4000	4000	4000	4000	24000
5.	Back-up CRC & Data Entry Operator	2000	2000	2000	2000	2000	1500	11500
6.	Subject Travel Allowance	1000	1000	1000	1000	1000	1000	6000
7.	Tonometry	100	100	100	100	100	100	600
8.	Slit lamp examination	100	100	100	100	100	100	600
9.	Fluorescein angiography (FA)	1500	NA	NA	NA	NA	NA	1500
10.	Optical Coherence Tomography (OCT)	1500	NA	1500	1500	1500	1500	7500
11.	Fundoscopy	500	500	500	500	500	500	3000
12.	ECG	650	NA	NA	NA	NA	650	1300
Total Cost Per Completed Subject								**200000**

Note: The study documents will be archived at the site for 5 years post study close-out visit. Study site will be paid archiving fee of Rs 50,000 for the same.

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Registrar
Swami Rama Himalayan University

Commercial Terms and Conditions

- Payment shall be made within 45 days of receipt of signedInvoice from the site. 20% of payment will be paid on site close out.
- All payments under this agreement are exclusive of GST, which will be charged additionally as per applicable rates.
- Per subject cost will be paid as mentioned above upon completion of each visit and activity and confirmation by site monitor of completion/verification ofeCRF for a properly qualified subject after each monitoring visit.
- The site team or institution (Swami Rama Himalayan University) shall raise study invoices on a monthly basis, including the HSN/SAC Code #998113.

Payee Details:For Principal Investigator, Co-I, Institutional Overhead 20%, Tonometry, Slit lamp examination, Fluorescein angiography (FA), Optical Coherence Tomography (OCT), Fundoscopy, ECG:

Payee Name	Swami Rama Himalayan University
Payee Address	Swami Rama Himalayan University, Swami Ram Nagar, Jolly Grant Dehradun 248016
Account Number	33082676422
PAN/TAX ID No:	AAAJH0463L
IFSC code	SBIN0010580
GST Number	05AAAJH0463LIZC
Contact	Dr. Nikku Yadav

Payee Details: For **CRC fees, Back-up CRC & Data Entry Operator, Subject Travel Allowance:**

Payee Name	KV CLINICAL RESEARCH PVT LTD
Payee Address	Off. No. 617 Sixth floor Golden Trade Centre New Rajendra Nagar Raipur-492001 (C.G)
Account Number	50200053851767
PAN/TAX ID No:	**AAICK3564G**
IFSC code	HDFC0001280
GST Number	22AAICK3564G1ZN
Contact	Dr. Kirti Kumar Patel, 9039939374

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Department of Ophthalmology
HIMS, Dehradun

For Clinical Research Network India	For Principal Investigator	For Institute/Site	For SMO
Signature: ..... Name: Mr. Yogesh Saini Title: Assistant Director Address: B-806,807, Advant Navis Business Park Plot #7, Noida-Greater Noida Expressway, Sector 142, Noida, Delhi-NCR, Uttar Pradesh 201305, India	Signature: ..... Name: Dr. Renu Dhasmana Dr. Renu Dhasmana Professor & Head Department of Ophthalmology HIMS, Dehradun Title: HOD & Vice Principal Address: Department of Ophthalmology, Himalayan Institute of Medical Sciences, Swami Rama Nagar, Doiwala, Dehradun 248140, Uttarakhand, India	Signature: ..... Name: Commander Challa Venkateswar (Retd.) Title: Registrar Address: Himalayan Institute of Medical Sciences, Swami Rama Nagar, Doiwala, Dehradun 248140, Uttarakhand, India	Signature: ..... Name: Dr. Kirti Patel Title: COO Address: Office No 616, 6th Floor, Golden Trade Center, New Rajendra Nagar, Raipur, Chhattisgarh 492001

WITNESS

NOTARY Rajender Singh Negi Advocate Dehradun District (U'khand) GOVT. OF UTTARAKHAND (INDIA)

ATTESTED (RAJENDER SINGH NEGI) Advocate & NOTARY Chamber No. 92, 1st Floor Opposite Bar Office Collectorate Court Compound Dehradun (Uttarakhand)