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CLINICAL TRIAL AGREEMENT

This Clinical Trial Agreement [Hereinafter referred to as "Agreement"] is entered into on 15 day JUNE of 2020 among

Raptim Research Pvt Ltd a company originally incorporated in the year 2005 and registered under Companies act, 1956 as having one of its office is located at A-242, TTC Industrial Area, Near Mahape Depot, Mahape MIDC, Navi Mumbai-400701, Maharashtra, India, [Hereinafter referred to as "CRO"] of the first part.

And

Dr., (PI Name) – Dr. Rashmi Mahajan, Professor & Head, Department of Skin & VD, SumandeepVidyapeeth and Institution Deemed to be University & Dhiraj Hospital, At & Po. Piparia, TalukaWaghodia, Dist. Vadodara, Gujarat 391760, [Hereinafter referred to as "Principal Investigator"] of the Second part

And

SumandeepVidyapeeth and Institution Deemed to be University, At & Po. Piparia, TalukaWaghodia, Dist. Vadodara, Gujarat 391760 through its "Registrar

30/11/2023

19/06/20

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

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Dr Chandramani. B. More [Hereinafter referred to as ""Institute"] of the third Part.

WHEREAS Sponsor, "Encube Ethicals Private Limited" having its registered office at "(Unit No. 24, Steelmade Industrial Estate, Marol Village, Andheri (E), Mumbai – 400059, Maharashtra, India)." [Hereinafter referred to as "Sponsor"] wishes to conduct clinical trial entitled "A multi-center, double-blind, randomized, parallel group, active and placebo-controlled in vivo clinical endpoint based bioequivalence study of Clindamycin Phosphate Topical Lotion Eq. 1% Base among subjects with Acne Vulgaris" **(Study Number BE/19/070)** [Hereafter referred to as "Study"] has engaged CRO to conduct this study.

AND WHEREAS CRO has already identified the Principal Investigator based on his/her experience and expertise and also Principal Investigator has sought permission from the Institution to conduct this study in the premises of the Institution. Hence CRO is desirous of engaging the said Principal Investigator and Institute for carrying out the Study.

NOW, THEREFORE, in consideration of the premises and the covenants, enter into this Agreement and do hereby agree with each other to the following:

1) Statement of work

1.1) "Study" shall be deemed to be "Clinical Trial" as defined in rule-GSR-227 New drug CT rule 2019 (including all amendments from time to time till present).

1.2) Principal Investigator and Institute will be responsible to conduct this study with strict compliance to approved Protocol, ICH-GCP and applicable laws and regulations prevailing in the country where clinical trial is conducted giving utmost importance to protect rights, safety and well-being of clinical trials subject.

1.3) CRO shall provide Principal Investigator with a sufficient quantity of study supplies to conduct the Study at investigational site in timely manner. Institute and Principal Investigator shall use Study Supplies in clinical trial subjects only for the purpose to conduct the Study in accordance with the Protocol; All These study supplies includes

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1.4) such as Study drug(s) Investigational Product (IP) and related devices/instruments, equipment, diary cards, paper CRF or blank informed consent forms and remain the sole property of CRO, unless otherwise designated. The Institute and Principal Investigator will be responsible for the return of excess, unused study supplies to the CRO or at CRO's option towards completion of study or earlier termination or may inform in writing for destruction by Institute and provide destruction certificate. In either case expense will be paid by CRO.

1.5) Study Timelines: Study Timelines for the purpose of this Agreement will be in accordance with Protocol and as conveyed by CRO from time to time.

2) Responsibilities And Obligations of the Principal Investigator

2.1) The Principal Investigator will conduct the study in the Institute in accordance with approved protocol, New Drug CT Rule 2019 (including amendments from time to time). and Indian Council of Medical Research (ICMR) Guidelines along with Helsinki and The International Conference on Harmonization of Technical Requirements for Registration of Pharmaceuticals for Human Use (ICH) Guidelines for international studies and all applicable laws and regulations prevailing in country during conduct of clinical trial.

2.2) Principal Investigator will have trained and experience staff as a part of his/her team throughout the study to perform study related activities after they have been trained on their role to be performed in the study. Principal Investigator may delegate and document delegation of his responsibilities to his/her team members who too will strict comply with obligations of Principal Investigator mentioned in section 2.2.

2.3) Principal Investigator will start performing study related activities only after fully execution of this Agreement by all parties who are signatory in this Agreement and after having IEC (Institute Ethics Committee) and regulatory approval are in place.

2.4) The Principal Investigator will ensure enrolment of trial participants after obtaining signed informed consent including audiovisual recording wherever applicable and also informing the provisions of adequate treatment and compensation for Serious Adverse Event (SAE) as per New Drug CT rule 2019 including amendments from time to time. In case of amendment to informed consent form, prompt consenting will be obtained by

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Principal Investigator on approved version of amendment consent form(ascent form , if required) with liberty to trial subjects to decide on further continuation in the study.

2.5) Principal Investigator will recruit only those trial participants into study who meet all Inclusion and Exclusion criteria for the study provided in the approved Protocol.

2.6) The Principal Investigator will be responsible for submission of study documents from CRO to IEC to obtain approval for conduct of study and forwarding IEC communications to CROs within a week of receipt of response which may either be comments for the need of any change in protocol or Patient Information Sheet (PIS) or approval to conduct said study in the Institute.

2.7) It will solely be Principal Investigator's responsibility to ensure trial participants are randomized correctly as per randomization schedule and administered Investigational Product (IP) only to assigned subjects enrol led in the trial as per Protocol. Principal Investigator will be responsible for proper account of receipt of IP; selection and storage of reserved (retention) samples; IP utilization by assigned subjects and return of unused IP to CRO/sponsor as well as prevent its use for any other purpose apart from Protocol.

2.8) The Principal Investigator shall report all serious and unexpected adverse events and/ or death to the Licensing Authority, CRO, and IEC as per New CT rule 2019 (including amendment from time to time)..

2.9) The Principal Investigator shall forward its report on Serious Adverse Event of Death after due analysis of all factors with his opinion to Chairman of IEC, Head of the Institute and the Licensing authority as per New CT rule 2019 (including amendments from time to time).

2.10) During and following a Clinical Trial Subject's participation in Study, the Principal Investigator shall ensure that prompt diagnosis and adequate medical care is provided to the participant (Clinical Trial Subject) for any adverse events.

2.11) The Principal Investigator will be responsible for keeping source of subject up to date, for proper and prompt filling of Case Report Form (CRF), preservation of investigation reports and recordings and resolution of any query generated from date being submitted. Where requested by CRO, Principal Investigator shall provide scan copy of source and other documents after masking subject's confidential information.

2.12) The Principal Investigator will make necessary arrangement for inspection of study related documents including signed informed consent form and Investigational Product (IP) etc. by CRO's monitor, official of regulatory agency or Institutional Ethics Committee (IEC) nominee.

2.13) In case of any deviation non-compliance/violation to approved Protocol, Principal Investigator will promptly document and notify to CRO and IEC.

2.14) The Principal Investigator will be responsible for obtaining IEC and CROs permission for storage of blood or tissue samples for future use.

The Principal Investigator shall not conduct additional research or obtain any additional biological samples (includes blood or tissue samples) apart from those specified in the Protocol from participating subjects unless it is approved in writing from CRO and applicable regulations plus in terms of subject safety. Once received, Principal Investigator will obtain necessary approval and permission for storage of these samples for future use.

2.15) The Principal Investigator will be responsible for providing progress report and any non-compliance report to Institutional Ethics Committee (IEC) and a copy to CRO within a week of occurrence or due date.

2.16) The Principal Investigator shall be responsible for obtaining CRO's permission before publication or conference presentation of any data.

2.17) Principal Investigator (PI) shall complete the Clinical Trial under his supervision as per the agreement and the Statutory provisions, but if for any reason he/she is unable to carry over the study it shall be his/her responsibility to hand over the study to either his/her Co-Principal Investigator (Co-PI) or to any of the Faculty members of the Institute as decided by the Head of Department of the PI or Director of Institute and obtain necessary approval of the Ethics Committee and the CRO.

3) Obligation and Responsibilities of the Institute:

1) To ensure study shall be conducted in compliance with the Protocol, Standard Operating Procedure (SOP) and applicable regulatory requirements.

2) Ensuring that the rights, safety and well-being of Clinical Trials Subject are protected.

3) Fulfillment of necessary obligations by Institutional Ethics Committee (IEC), Principal Investigator (PI) and supporting staff conducting said study.
4) Protection of confidentiality, rights, safety and wellbeing of clinical trial participants.
5) Provide necessary infrastructure support to PI to conduct study as required by Protocol.
6) Communicating with IEC and obtaining approval for the Clinical Trial Protocol, written informed consent and other trial related study documents. Ensure Principal Investigator communicates with IEC to obtain approval for the Clinical Trial Protocol, written informed consent and other trial related study documents including amendments.
7) Approval of study from EC within 6-8 weeks of receipt of Investigator's brochure, protocol including Patient Information Sheet (PIS) & Case Report Form (CRF), regulatory approvals, draft Clinical Trial Agreement (CTA), Insurance policy and IEC fee from CRO.
8) Approval of amendments if any of receipt of documents.
9) The confidentiality of record that could identify Clinical Trial subject should be protected and maintained.
10) Ensuring accuracy, completeness, legibility and timelines of the Data being reported to the CRO in Case Report Forms (CRFs) and in all required reports.
11) Safety reporting as per New Drug CT rule 2019(including amendments from time to time) and/or CRO policy.
12) Provide adequate treatment and compensation for Serious Adverse Event (SAE) to trial subjects and ensure compensation received from CRO are paid to these subjects.
13) Review of progress report, Data and Safety Monitoring Board (DSMB) report & Serious Adverse Event (SAE) from other centers and accordingly provide decision on termination of study or its extension beyond approved period.
14) Review of SAE at site and necessary action within the time frame decided by regulatory agencies. Review of SAE and ensure all necessary requirements including those of prevailing regulatory guidelines are fulfilled by Institute itself, Principal Investigator and IEC.

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15) In case EC recommends of termination of study in view of safety and benefit of clinical trial subjects, Institute will ensure study is properly terminated by Principal Investigator as per CRO instructions while ensuring no risk to trial subjects,.
16) Provide adequate storage facility for biological samples including blood and tissue of clinical trial subjects in case Protocol requires it to be stored for future use.
17) Institutional clearance for samples to be sent abroad non-pharmacokinetic studies. Institutional clearance for samples to be sent abroad for analysis where required studies.
18) Facilitate visit of CRO's monitor or its representative or representative of regulatory agencies.
19) Upon request of the monitor, auditor, Institutional Ethics Committee or applicable regulatory authority, Institute should make available for direct access all requested trial related records including signed informed consent form.
20) Safeguarding Intellectual property rights (IPR) of CRO.
21) Archiving of data for 15 years after completion of all planned regulatory activities as per prevailing laws and regulations of that country (ies) for which study was conducted or as mentioned in the Protocol or for longer period if required by CRO/Regulatory agency).
22) Providing alternate Principal Investigator (PI) if PI unable to continue (which may include transfer, retirement etc).
23) Audited statement of utilization of Funds.

4) Responsibilities and Obligation of the CRO

2.1) To provide investigator's brochure, Protocol, Case Report Form (CRF) draft Clinical Trial Agreement (CTA), Insurance policy from an Indian Insurance company and regulatory approvals including other study related documents and supplies.

2.2) To provide required devices/instruments and/or equipments to support Principal Investigator to conduct said study.

2.3) To provide adequate supplies of Investigational Product (IP) and comparator prepared under proper quality control as per regulatory norms.

2.4) To provide Insurance cover for treatment and compensation of Serious Adverse Event (SAE) including any diagnostic procedure performed and an undertaking to supplement any amount not covered by the Insurance Company. CRO will also provide copy of Policy to the Principal Investigator.

2.5) Assist Principle Investigator for storage of biological samples drawn as per Protocol for future study if requested by Principle Investigator.

2.6) Provide a copy of Clinical Study Report (CSR)/summary report at the end of study or at termination of the study to Principal Investigator and to IEC.

2.7) To submit a status report on the Clinical Trial to the Licensing Authority at the prescribed Periodicity;

2.8) Appropriately acknowledge Principal Investigator for his/her contribution in the study in any publication as deemed suitable by CRO.

2.9) To define and follow procedure for premature termination.

5) Debarment

Principal Investigator and Institution certifies that they and any of their facility or person attached to such facility whose services are used for conduct of study like laboratory are not debarred by Indian law or US law or by law of any country where submissions are planned to be made. Principal Investigator and Institution will promptly inform CRO of any such debar being aware during the course of study until one year post completion of this study on within

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30 days from "Effective Date of Termination" mentioned in section 19.4 of this agreement and will extend full cooperation to CRO

6) Financial Compensation

72.1.6.1) CRO on behalf of Sponsor agrees that any injury or death or injury to child in-utero of the clinical trial subject occurring in clinical trial due to following reasons shall be considered as clinical trial related injury or death or injury to a child in-utero and the subject or his nominee, as the case may be, will be entitled to receive from the Sponsor financial compensation for such injury or death or injury to a child in utero as per the notification decided by of the Drug Controller General of India (DCGI) issued from time to time.

a) Adverse effect of Investigational Product(s);
b) Failure of Investigational Product to provide intended therapeutic effect;
c) For injury to a child in utero because of the participation of parent in clinical trial provided adequate method of contraception as specified in Protocol was used throughout the duration mentioned in the Protocol;
d) Any clinical trial procedures involved in the Study.

8) Indemnification:

CRO agrees to hold harmless Principal Investigator, his/her staff involved in clinical trial, Institution at which the study is conducted and the IEC that approved the study. CRO indemnifies them of any claim filed by subject or his/her legal representative or the nominee for any adverse event to subject due to participation in the study provided approved protocol was followed excluding negligence or misconduct by Principal Investigator, his/her staff or Institution or IEC . Principal Investigator will promptly inform CRO of any such notice and will extend full cooperation to CRO.

9) Undertaking and Representation of Principal Investigator:

Principal Investigator hereby represents that he/she has furnished an undertaking to Licensing Authority in the format given in New Drug CT rule 2019 including amendments from time to time.

10) Undertaking and Representation of Institute:

Institute hereby represents that: - It has constituted the Ethics Committee (EC) as per the guidelines given in the Gazette of India & it has been registered with the Drug Controller General of India (DCGI) vide letter No: ECR/85/Inst/GJ/2013/RR-19 dated 08-Aug-2019.

10.1) EC SOP is in compliance with Good Clinical Practice (GCP) guidelines and applicable regulations;

10.2) It will ensure that EC will fulfills its responsibilities as per provisions of New Drug CT rule 2019 including amendments from time to time.

11) Undertaking and Representation of CRO:

CRO hereby understands and represents that: - It has furnished an undertaking on behalf of Sponsor along with the application for Clinical Trial Permission to the Licensing Authority to provide compensation in the case of clinical trial related injury or death for which subjects will be entitled to compensation; as per provisions of rule New Drug CT rule 2019.

12) Administration:

12.1) Overall responsibilities to conduct study at Institute will rest with Principal Investigator.

12.2) The following study plan will apply to the Study:

a) Institute's Enrollment Maximum (i.e. Total number of enrolled subjected expected from site) shall be as mentioned in annexure-A of this agreement. However, if the Institute and Principal Investigator are unable to enroll patients for the Study within 3-4 months of Site initiation CRO will be having the authority to change the Institute's Enrollment Maximum in a unilateral manner or close the site.

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b) Subject to applicable law: CRO and Institute without any further obligation mutually may agree in writing to modify Institute's Enrollment Maximum at any stage.

c) All subject visits will be conducted as proposed in the Protocol. The CRO will be informed if a subject visit exceeds visit window period along with reason of delay.

d) Case Report Forms ("CRFs") information associated with a subject's visit must be satisfactorily completed within 3 working days after the subject's visit or, if applicable, receipt of the subject's test results.

e) All Data Queries from CRO or Sponsor or from Data Management group as applicable must be completed and returned to CRO within a time frame mutually negotiated.

f) Any intentional changes of inclusion/exclusion criteria by the Principal Investigator or Study team without approval from CRO will not be the liability of CRO.

13) Trial Drug; Materials Transfer; Records Retention;

13.1) Investigational Product (IP)/device (instrument) or equipment:

a) Institute and Principal Investigator acknowledge that the investigational product or device (instrument) or equipment is owned or controlled by CRO on behalf of the sponsor and that neither the terms of this Agreement nor the Protocol, nor any activities conducted by Institute or Principal Investigator, shall be construed to grant to either Institute or Principal Investigator any rights in or to the Compound/ Investigational Product (IP).

b) CRO will provide the Investigational Product (IP) which includes test drug or reference drug to be administered to trial subjects as part of the Trial with no cost to Institute for administering or dispensing solely by or under the supervision of Principal Investigator or sub-investigator to trial subjects at the trial site in Strict compliance with the Protocol.

c) Principal Investigator shall be responsible to randomly select quantity of IP as directed by CRO/sponsor for 'Reserved (retention) samples' and its storage securely throughout the trial period to avoid its accidental usage.

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d) Institute and Principal Investigator shall store and use Investigational Product (IP) solely to conduct the Trial in strict compliance with the Protocol and for no other purpose, and shall not transfer the Investigational Product (IP) to any third parties. Institute and Principal Investigator shall handle, store, ship and dispose of the Investigational Product (IP) as directed by CRO and in compliance with all applicable laws, rules and regulations.

e) Institute and Principal Investigator will ensure empty and partially used Investigational Product (IP) container and any unused Investigational Product (IP) remaining at the trial close-out visit at the trial Site or upon early termination of this Agreement are either disposed of or returned to CRO in accordance with the Protocol or at CRO's option as directed by CRO at the time of site closure. All clinical retention IP samples will be stored at the clinical site or be stored at some 3rd party until further instructions by the sponsor for its destruction.

f) Neither Principal Investigator nor Institute will impose any obligation, express or implied, on CRO/Sponsor to purchase, prescribe, provide favorable formulary status for or otherwise to support trial product.

g) Unless specified in the Protocol, Principal Investigator will not modify the Investigational Product (IP) or its container. If the Institute policy requires any modification to the Investigational Product (IP) container, such modification must be approved in advance in writing by Sponsor.

13.2) Records Maintenance and Retention:

a) Principal Investigator and Institute will maintain clinical trial related records relating to Investigational Product (IP) and other trial subject documents including but not limited to, signed consent form and audiovisual documents if applicable, medical records, charts pertaining to individual trial subjects, "Case Report Forms ("CRF") accounting records, notes, laboratory reports, and data. Institution will permit Principal Investigator to retain these documents for a period of at least 5 yrs or longer as mentioned in below Section-23, Record Keeping, after completion of all regulatory activity as per applicable laws and regulations for the country (ies) for which study was conducted or in accordance with Protocol or earlier termination of the trial or till

the time CRO notifies to Principal Investigator in writing for return or destruction study documents.

14) Representation and Warranties

14.1) Principal Investigator and Institute represents and warrants that it has the legal authority to enter into this Agreement and that the terms of this Agreement are not in conflict with any other agreements to which it is legally bound. Institute shall ensure that Principal Investigator will not enter into any agreement or engage in any activities that would materially impair its or his /her ability to complete the trial in accordance with this Agreement and the Protocol.

14.2) Institute represents and warrants that the Principal Investigator is qualified as a medical practitioner under applicable laws and regulations.

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15) Confidentiality

15.1) Institute will (and will cause Principal Investigator and trial personnel appointed by PI to) keep strictly confidential and not disclose to third parties all information provided by or on behalf of subject or of data that is generated, discovered, or obtained by any of the Party signatory to this agreement as a result of the trial (other than patient medical records), including the trial results, trial inventions and information related thereto (Confidential Information). Institute and Investigator will use, and will ensure trial personnel to use, Confidential Information only for purposes of the trial. The obligations of this Section will survive expiration or termination of this Agreement and can be maintained in good faith. Confidential Information will not include information that:

a) Is or becomes publically available through no fault of Investigator or Institution.

b) Was known to Principal Investigator or Institute without obligation of confidentiality prior to receiving it either directly or indirectly from other sources Under this Agreement, as demonstrated by written records predating the date it was learned by Investigator or Institute form other source.

c) Is disclosed to Principal Investigator or Institution by a third party without violation of law or any obligation of confidentiality; or

d) Can be shown by written records of Principal Investigator or Institution to have been independently developed by Principal Investigator or Institution without reference to or reliance upon any Confidential Information.

15.2) Notwithstanding any other provision of this Agreement, Institute and Principal Investigator may disclose Confidential Information to the extent required.

a) To comply with an applicable law, rule regulation or government order, after prompt notice to CRO provided that Investigator and Institute cooperate with CRO efforts to limit such disclosure by appropriate legal means:

b) To protect any trial subject's safety or provide appropriate medical care for any trial subject, or to prevent a public health emergency with prompt notice to CRO

c) For purposes of insurance or reimbursement by a third party or pay for medical treatment of trial subject related to the procedures included in the Protocol.

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16) Return of Confidential Information:

Upon either (i) the completion of the Trial or termination of this Agreement; or (ii) CRO's request in writing for any reason, Institute will immediately cease use of all Confidential Information, and will promptly either return to CRO or if instructed by CRO destroy all Confidential Information, including any copies, extracts, summaries, or derivative works thereof, and certify in writing to CRO the completion of such return and/or destruction, provided, however, that Institute may retain one copy of Confidential Information in its legal archives solely for the purpose of monitoring its surviving obligations under this Agreement.

17) Trial Results and Inventions:

17.1) CRO, on behalf of the sponsor, owns all data generated from the trial, trial results, Confidential information, Case Report Forms (CRFs) and all other information generated as a result of or in connection with the conduct of the trial, excluding Institution's patient medical records and Principal Investigator's personal notes and hereby grants to the Institute a nonexclusive, non–transferable, non-sub licensable right to use the trial results solely for its own internal, non-commercial research, patient care, and educational purposes.

17.2) All inventions, ideas, methods, works of authorship, know-how or discoveries that are made, conceived, or reduced to practice by Institute, Principal Investigator or trial personnel: (i) as a result of or in connection with the conduct of the trial (ii) that incorporate or use Confidential information: or (iii) that are directly related to the compound and in each case together will all intellectual property rights relating thereto (collectively, Trial Inventions"), will be the sole and exclusive property of CRO or its designee. Institute and Principal Investigator will promptly disclose all trial Investigations to CRO in writing and interest in all trial investigations to CRO or its

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designee. At CRO's request and expense, Institute shall take and shall cause Principal Investigator and trial personnel to take, all additional actions as it deems necessary taking into consideration interest of CRO and Sponsor in Trial Investigations or to obtain patents or otherwise protect the interest of CRO or its designee in Trial Investigations.

18) Payment:

18.1) In consideration for conducting the Study, CRO shall pay to Institute and Principal Investigator as described in Annexure-A. CRO will not make further payments, towards study visits, procedures, or other work associated with a Study subject if CRO determines that the clinical trial subject's data is not evaluable because of a violation of the Protocol by Principal Investigator or Study Staff.

18.2) CRO shall pay on a per subject cost for each satisfactorily completed subject (as defined below) in accordance with Annexure-A as attached to this Agreement. Only if a subject is discontinued for reason stipulated in the Protocol, the Institute and Principal Investigator shall be paid a prorated rate for work completed

a) Per Subject Costs: Payments will be made on per completed subject basis, in accordance with Annexure-A. The estimated total amount per clinical trial subject listed in Annexure-A is calculated for a clinical trial subject that completes all the study visits. Payment for Screening Visit shall be paid for consented clinical trial subjects in whom all screening procedures are performed. All the visit cost includes Institutional overhead, staff fees and applicable taxes from time to time, excluding GST.

b) The per subject costs is a fixed fee per subject which includes all costs and honoraria, including but not limited to:

- All study related activities such as conduct of visit assessment and CRF completion time and efforts of Principal Investigator/s and other Institute's study personnel including all manpower cost involved in the study conduct
- Site coordinator / Site Management Organization (SMO).
- All diagnostic test and other investigations (ECG, Chest X-ray, Spinal X-ray etc.)

- Housing or hospital stays including subjects including meals.
- Subject Travel Reimbursement / compensation.
- All Institutional overhead costs.
- Usage of instruments/ equipments which during the study should be having for proper instrument ID, their maintenance and calibration/annual maintenance record.
- Miscellaneous (telephone, fax, courier, storage cupboards and maintenance of Institute infrastructure).

c) Subjected to the terms of Protocol, a completed and evaluable subject means:

i) Who is enrolled for the Study according to inclusion and exclusion criteria and has completed all study visits with the Protocol specified procedures/assessments.

ii) For whom all sources, CRF and other Study related documents are completed as per protocol requirements

iii) For whom all Data are accurately and completely documented and transcribed in CRF.

iv) All data queries generated were resolved completely under mutually agreed timely manner.

18.3) Screen Failures/ Drop-outs: For drop-outs payment will be made by CRO on a pro-rated basis for the number of completed visits and for screen failure it will be according to details mentioned in Annexure-A

18.4) Institutional Ethics Committee: Apart from the payment mentioned in Annexure-A, CRO will pay for Institutional Ethics Committee fees.

18.5) Archival of study documents and reserved samples for a duration of 5 years after site closure will be paid as per details mentioned in Annexure-A.

18.6) Set-Up Fees: **Where Institute requires**, CRO will pay the Institute an initial advance amount of **INR 15,000** within 15 days after obtaining the Institutional Ethics Committee and necessary regulatory approval. This up-front advance payment would be exclusive of Institutional overhead and service charges and shall be deducted/ adjusted on pro-rata basis from further subsequent payments.

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18.7) Hospitalization costs: Apart from study specific hospitalization, any hospitalization charges related to Serious Adverse Event (SAE) shall be paid by CRO on behalf of Sponsor to the clinical trial subject.

18.8) CRO will release the funds to Institute or Principal Investigator for each clinical trial subject as per the study schedule for completed visits. However, it will be the obligation of Principal Investigator to pay the clinical trial subject reimbursement on a pro rata basis study period wise.

18.9) Payment towards Actuals: Principal Investigator will be reimbursed for purchase of medicines as a part of standard of care or concomitant medication as per Protocol along with any ancillaries. Principal Investigator to provide a copy invoice or other documentation clearly substantiating that the expenditures were actual and reasonable.

18.10) The Principal Investigator will not receive any direct or indirect payment from subject(s) participating in the Study or third-party payers for any material, treatment or service that is required by the Protocol.

18.11) Refund of Payment: In the event there is a refund due to CRO at the time of termination of this Agreement by any party, the Institute agrees to remit the same to CRO within sixty (60) days of the effective termination date (definition of which is mentioned in Section 22 below).

18.12) Tax deduction: All fees and amounts listed are inclusive of applicable tax (TDS- Tax Deduction at Source) prevailing from time to time. Prevailing TDS rate will be deducted from each payment disbursed to the Institute for the Study as per the applicable existing tax laws in the country. Certificate for the tax deducted at source will be provided at the end of the financial year.

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19) Use of other parties' names:

The Principal Investigator and Institute shall not use CRO/Sponsor name or the name of any party hereto in connection with any advertising or promotion of any product or service without the prior written permission from CRO/Sponsor.

20) No joint venture etc.

This Agreement shall not constitute, create, or in any way be interpreted as, a joint venture, partnership, or business organization of any kind.

21) Monitoring; Audit; Regulatory Inspection:

21.1) The Principal Investigator and Institute shall permit authorized personnel of the CRO/ CRO designate, any Regulatory Authority and EC to inspect the facilities of the Investigational Site before, during and after the Study.

21.2) The Principal Investigator and Institute shall notify to the CRO immediately by letter or mail if the Drugs Controller General-India, or any other governmental or regulatory authority requests permission to or does inspect the Principal Investigator and Institute's facilities or research records relating to this study whenever and will provide in writing to the inspecting authority copies of all materials, correspondence, statements, forms and records which the Principal Investigator and Institute receives, obtains, or generates pursuant to any such study.

21.3) The Principal Investigator and Institute will permit the CRO to; (a) Examine, inspect and audit the work performed as a part of the study and the facilities, systems, instruments and equipment used with which the study related activities are conducted under this Agreement as a part of study. (b) Inspect and retrieve documents and records related to such Study.

21.4) The Principal Investigator will promptly resolve any discrepancies that are identified in Study data or subject's medical record during monitoring, audit or during regulatory inspection.

21.5) The Principal Investigator will promptly intimate to CRO about findings generated from audit or regulatory inspection and may take assistance of CRO in responding to the findings.

21.6) The obligations of this Section shall beyond the expiration or termination of this Agreement and can be maintained in good faith.

22) Term; Waiver; Severability (The trial on its time extended):

22.1) This Agreement will become effective and fully executed after by the last signatory signs the agreement and shall continue in effect for the full duration of the study according to the Protocol unless extended by consent of all parties to this Agreement or sooner earlier terminated in accordance with the provisions of this Agreement.

22.2) This Agreement will be in force for a period of the trial and its time extended from the date of its signing. The term of this Agreement may be extended by consent of all parties to this Agreement.

22.3) Unless earlier terminated in accordance with the provisions of this Agreement, the term of this Agreement shall commence on the Effective Date. The Date of execution of this Agreement shall be the Effective Date.

22.4) None of the obligations under this agreement will be assigned by Principal Investigator and Institute to another without prior written approval from CRO.

22.5) This Agreement may be terminated by any party upon giving at least a thirty (30) days written notice to that effect to the other parties. The day following the 30th day of such notice shall be "Effective Date of Termination".

22.6) Any notice under this Agreement will be given in writing to:

Raptim Research Private Limited and to Principal Investigator at their address provided in signatory

23) Effect of termination

This agreement will be terminated upon any of the following events:

1) By EC or Regulatory agency (DCGI).

2) Early termination of study by Sponsor or Principal Investigator or Institute or by CRO.

23.1) Upon notice of termination of this Agreement by either Institute or CRO or Principal Investigator, Principal Investigator shall cease enrolling clinical trial subjects into the study, and shall proceed to discontinue ongoing subjects from study as soon as is medically practicable.

23.2) Upon notice of termination of this Agreement by Institute or CRO or Principal Investigator, Institute and/or Principal Investigator shall use reasonable efforts to revoke any financial obligations incurred and shall avoid incurring any additional costs in connection with the study. Institute shall be compensated only for study-related work actually performed or reimbursed only for expenses actually and reasonably incurred through the effective date of termination which CRO has agreed to pay as part of the study under this Agreement. If, upon the Effective Date of Termination, CRO has advanced funds which remain unutilized or surplus, Institute shall repay such funds within sixty (60) days of the Effective Date of Termination. In the event Institute fails to repay such funds in a timely manner, CRO may deduct an equivalent amount from any payment then or later due from CRO to Institute under this or any other arrangement between the parties.

23.3) Upon termination of this Agreement, all unused Materials and all CRO Confidential Information (except for such records that Institute is required by law or regulation to retain) in Institute's or Principal Investigator's possession shall be promptly delivered to CRO at CRO's expense, or, at CRO's option, destroyed with the destruction certified in writing.

24) Record keeping

Institute and Principal Investigator shall retain for archival of all records and documents pertaining to the study under appropriate storage conditions so that they are preserve them for a period of 15 years after completion of all regulatory activity as per applicable laws and regulations for the country (ies) for which study was conducted or in accordance with Protocol unless CRO provides in writing for return or destruction of records and documents prior to retention period. At the end of retention period if no response is received from CRO,

Institute can forward all study related documents retained by Institute to CRO at CRO's expense. CRO can request Institute to retain study related documents for longer period at CRO's expense for which Agreement will be signed. Institute may choose to retain these study related documents for longer time on request of CRO at different location from earlier one with written approval from CRO.

25) Publication

The parties acknowledge that the Sponsor will retain ownership of all original data generated from this study. Data generated during the Clinical Trial Study is the sole property of the Sponsor & CRO. Therefore, Principal Investigator agrees not to publish or present the results or any information derived from the study but Sponsor may decide to include his/her name in any publication either as author or as participant in the study.

26) Miscellaneous

Parties to this Agreement shall comply with the current provision of New Drug CT rule 2019 including amendments from time to time. For providing insurance to Clinical Trial Subjects in case of injuries or death, the Sponsor/CRO to this Agreement have tied up with insurance company This insurance shall be extended from time to time till the expiry of Agreement.

27) Governing Law

The validity, interpretation, and performance of this Agreement shall be governed and construed in accordance with the laws of INDIA as applicable in the State of Mumbai.

28) Jurisdiction

The place of jurisdiction for any dispute or claim before a court or an arbitrator shall be Mumbai notwithstanding any other provision to the contrary in any law in this regard.

29) Arbitration

All disputes or claims whatsoever arising out of or in respect of the terms and conditions of this agreement or relating to the admissibility or liability or quantity of compensation or damages payable to or by any of the parties to this agreement to the trial subject or his/her legal representative or the nominee or by one party against another shall be referred by the

SUMANDEEP VIDYAPEETH

aggrieved party or person to the arbitration of a sole-arbitrator to be appointed by the Chairman of the Institutional Ethics Committee of the Institute within 30 days of the receipt of a written request by the aggrieved. The Indian Arbitration and conciliation Act 1996 as amended from time to time shall be applicable to such arbitration proceedings subject to the exception that the trial subject or his/her legal representative or the nominee shall not be liable to pay the cost of arbitration. The award of the arbitrator shall be final and binding on all the parties thereto.

30) Amendment

This Agreement may only be amended by the mutual written consent of the parties hereto. The parties agree that this Agreement constitutes the sole, full and complete Agreement by and between the parties and supersedes all other written and oral Agreements and representation between the parties with respect to the said study. No amendments, changes, additions, deletions, or modifications to or of this Agreement shall be valid unless reduced to writing and signed by the parties.

Acceptance of Agreement:

All the below signatories confirm that they have read and understood all the clauses of this Agreement:

SUMANDEEP VIDYAPEETH

Principal Investigator Name & Address Of PI:
Dr. RashmiMahajan
Professor & Head
Department of Skin & VD
SumandeepVidyapeeth an Institution Deemed to be University & Dhiraj Hospital
At & Po. Piparia, Ta. Waghodia Vadodara 391760
Signature and date: 12th June 2020

Stamp

Institution Signatory Name, Address & Designation:
Dr. Chandramani. B. More
Registrar
SumandeepVidyapeeth an Institution Deemed to be University

Signature and date: 15/06/2020.

Stamp

DR. RASHMI MAHAJAN
(M.D. SKIN & V.D.)
Professor & Head
Department of Dermatology
Dhiraj Hospital, Pipariya,
Reg. No. G-16731

Mr. Vidhu Shekhar Mishra, AGM-Raptim:

Signature and date: 05 June 2020

Stamp

SUMANDEEP VIDYAPEETH

Payee Details:

The research grant payments will be made to the following payee and address:

Payee Name: Research Cell SumandeepVidyapeeth

PAN No.: AAATK4485H

Payee Bank Name: Indian Overseas Bank

Account no.: 178802000000131

IFSC Code: IOBA0001788

ANNEXURE- A: INVESTIGATOR GRANT PER COMPLETED SUBJECT

a) Total number of enrolled subjects expected from site: **110** (referred as Institute's Enrollment Maximum).

b) For every Screen Failure subject who could not proceed for Randomization into the Study as per the criteria of the Protocol, **Rs 2000** (in words "Two Thousand Only") shall be paid to a maximum of **12** subjects i.e for every 6 subjects enrolled one screen failure will be considered (6:1 ratio) and paid which shall be inclusive of all charges. After which, no payment shall be paid additional screen failure subjects apart from subject's travel compensation.

c) On completion of entire study as per Protocol, **Rs 28,480** (in words "Twenty EightThousand Four Hundred Eighty Only") shall be paid.

CTA Break Up	Screening Visit	Baseline and Randomization	Interim visit (Safety and compliance)			End of treatment	Telephonic Safety Follow Up	Total
	Visit 1	Visit 1	Visit 3	Visit 4	Visit 5	Visit 6		
Investigator Consultation	3500	3500	3000	3000	3000	3000	1300	20300
Patient reimbursement	500	500	500	500	500	500	0	3000
IOH (20 %)	800	800	700	700	700	700	260	4660
Per Patient + IOH	4800	4800	4200	4200	4200	4200	1560	27960
Archival Charges								500
Total								28460

d) No other payments shall be made to Investigator and or Institution apart from Institutional Ethics Committee Fees which shall be paid on submission of invoice.

e) Above grant is inclusive of subject travel and compensation, hospitalization charges, subject's meal, local laboratory assessments as per Protocol, required infra-structure for conduct of this study, calibration/maintenance cost for study related equipments,etc. For further details, please refer **section 17** of this agreement that covers all expenses under Per Subject Cost.

f) GST of 18% shall be additional to above mentioned Per Subject fees.

g) Per Subject fees shall be paid once Data Management and Quality Assurance confirms that there is no query in the retrieved CRF pages.

h) 20% of the Per Subject fees shall be paid after data base lock but before site closure.

i) Invoice must be submitted to CRO monitor for all costs to be paid by CRO.

j) All undisputed invoices shall be paid within 45 days of receipt.

k) No screen failure charges shall be paid in the absence of a documented screening visit.

Attested CTC

30/11/2023

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