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24AC 858800

iDD Research Solutions pvt Ltd. Chennai.

06 NOV 2023

T.V.OMPRAKASH (S.V.)
195,MUTHURANGAM ROAD
W.TAMBARAM, CHENNAI-45.
No.9593 / B1/2000 DT.7.9.2000
Cell:98413 19588.

STATEMENT OF AGREEMENT

(Clinical Trial Agreement)

between

Dr. Nand Kishore

(Hereinafter referred to as the "Investigator")

And

Swami Rama Himalayan University, Dehradun

For its constituent college Himalayan Institute of Medical Sciences

(Hereinafter referred to as the "Institution")

Swami Rama Himalayan University
Registrar

and

iDD Research Solutions Pvt. Ltd.

(Hereinafter referred to as "CRO")

Protocol number:GB_LAB_001_21

1 Introduction

a) CRO, a clinical research organization, is pleased that our discussions have resulted in your agreement to participate in and conduct this collaborative clinical research trial, titled "**A post marketing surveillance study to assess safety and tolerability of Liposomal Amphotericin B Injection in patients with Invasive Fungal Infection who are refractory to or intolerant of conventional Amphotericin B therapy**"and "Gufic Biosciences, (the "Trial" and the "Sponsor" respectively)."

b)In order to make this Trial mutually rewarding, it is essential that we are in agreement with regard to the basic policies applicable to the Trial. Accordingly, this Clinical Trial Agreement in conjunction with Sponsor's protocol no. GB_LAB_001_21and A post marketing surveillance study to assess safety and tolerability of Liposomal Amphotericin B Injection in patients with Invasive Fungal Infection who are refractory to or intolerant of conventional Amphotericin B therapy. which is incorporated by reference herein, will serve together as an agreement, delineating the terms and conditions applicable (the "Agreement"). Where there is a conflict between the terms of the Protocol and the Agreement, the terms of the Agreement shall prevail except where the conflict relates to medical, ethical or clinical issues in which case the Protocol shall prevail.

2 Trial Conduct

a.The scope and nature of the Trial and services to be performed by the Institution **at Himalayan Institute of Medical Sciences** should be in accordance with the Protocol.

b. As it is essential that the Trial is carried out exactly in accordance with the terms of the Protocol, each of the Institution and Investigator agrees to study the Protocol and satisfy themselves that they fully understand it and are able to conduct the Trial in the manner specified therein. Any change to the terms of this Agreement shall be valid only if the change is made by mutual written agreement of authorised representatives of all parties hereto. No changes or deviations to the Protocol should be implemented without agreement by the Sponsor and prior review and documented approval from the Ethics Committee ("EC"), unless to eliminate an immediate hazard to volunteers.

c. The Institution and Investigator shall be thoroughly familiar with the appropriate use of the Trial supplies (as defined below), as described in the Protocol, the current investigator's brochure, the product information leaflet, if any, and all information provided to them in connection with the Trial.

d. Accordingly the Institution and the Investigator each agree to carry out the Trial in accordance with:

- this Agreement;
- the Protocol;
- the provisions of the current applicable version of the World Medical Association's Declaration of Helsinki, applicable national` laws, regulations and guidelines including without limitation the New Drugs and Clinical Trials Rules, 2019, Ethical Guidelines for Biomedical Research on Human Subjects" laid down by Indian Council of Medical Research (ICMR), Indian GCP, and the Guideline for Good Clinical Practice (GCP) of the International Conference on Harmonisation (ICH) of Technical Requirements for the Registration of Pharmaceuticals for Human Use and with other generally accepted applicable Guidelines of the ICH a copy of which has been provided to Investigator. (ICH Topic E6, Consolidated Guideline 1.5.96)

3 Investigator

Institution's investigator, **(Dr.) Nand Kishore ("Investigator")** will be responsible for the direction and supervision of all Study efforts in accordance with the Protocol and this Agreement. Investigator and Institution shall provide all of the services contemplated herein through fully trained and competent Study Staff (as defined below) having a skill level appropriate for the tasks assigned to them and shall ensure that all Study Staff (as defined below) comply with the terms of this Agreement and the Protocol. "Study Staff" means (i) employees, officers, and directors of Institution, including without limitation the Investigator, and (ii) any agents, contractors or other third parties approved by Sponsor/CRO in writing in accordance with Article 15.In the event that Investigator leaves or is removed from the Institution, then Institution shall, within ten (10) days of becoming aware of such departure by Investigator, provide written notice of such event to Sponsor/CRO. Any successor to Investigator must be approved, in writing, by Sponsor and such successor shall be required to agree to all the terms and conditions of the Protocol and this Agreement and to sign each such document as evidence of such agreement (although failure to so sign will not relieve such successor from abiding with all the terms and conditions of the Protocol and this Agreement).

Institution represents and warrants that it will not use in any capacity, in connection with any services to be performed under this Agreement, any individual who has been debarred pursuant to any applicable laws or regulations, or any applicable professional code of ethics.

Institution agrees to immediately inform Sponsor in writing if any person who is performing services hereunder is debarred or if any action, suit, claim, investigation or legal or administrative proceeding is pending, or, to the best of Institution's knowledge, is threatened, relating to the debarment of Institution or any person performing services hereunder. Investigator represents and warrants that no action, suit, claim investigation or legal or administrative proceeding is pending or threatened relating to Investigator's debarment and Investigator agrees to immediately inform Sponsor in writing if any such action, suit, claim, investigation or legal or administrative proceeding is threatened or commenced for Investigator's debarment.

If information collected on the form changes during the course of the Study or within one year after the last subject has completed the Study as specified in the Protocol, Investigator and the other applicable Study Staff are required to inform Sponsor of such change.

4 Commencement and Duration

The Trial will commence following signature of this Agreement as soon as the Institution and the Investigator have received Ethics Committee (EC) approval and obtained a list of members and any national regulatory approval as appropriate has been obtained by Sponsor, Investigator and Institution. It is expected that a minimum of 25volunteers will be randomised to treatment at **Site name: Himalayan Institute of Medical Sciences**. Targeted subjects to the site will be increase or decrease upon the CRO or Sponsor discretion. At any time during the trial, if it becomes apparent that either Institution or Investigator will be unable to complete the Trial on schedule or enroll the number of volunteers specified, Institution or Investigator will notify CRO immediately to make appropriate alternative arrangements. Similarly, if CRO considers that the Institution's recruitment is unduly slow then the target number of volunteers may be reduced or the Trial terminated in accordance with section 15 below. Furthermore, if at any time during the course of the Trial the Institution and the Investigator have not reached their own enrolment target but the overall target of the Trial has been reached, Institution and Investigator will upon written request by Sponsor or CRO immediately stop recruitment. Sponsor will endeavor to provide Trial supplies in order to facilitate the agreed time lines; however, neither Investigator, Institution nor CRO will be held liable for any events that may result from delays that may occur.

5 Compensation

a. Sponsor will provide the financial support set out in the budget (Appendix A) and upon completion by Institution and Investigator of the Payment Invoice (Appendix B), for the conduct of the Trial in accordance with "National Ethical Guidelines for Biomedical and Health Research involving Human Participants, 2017, Indian GCP, Rule 122DAA New Drugs and Clinical Trials Rules, 2019, as applicable.

Swami Rama Himalayan University
Registrar

b. Each of Institution and Investigator will make all necessary notifications, filings and arrangements with the appropriate authorities in connection with their respective tax affairs and shall deal directly with such authorities and shall be exclusively responsible in respect of any liability for income, social, corporate or other taxes, which shall be incurred as a result of this Agreement.

6 Confidentiality, Data Protection and Intellectual Property

a. All information provided to the Investigator and the Institution either by the Sponsor or CRO or a third party for the purpose of carrying out the Trial and any data, information or results arising from the Trial will be considered confidential information and may only be disclosed to those who have a need to know such information for the sole purpose of administering the Trial. The confidential information shall remain confidential until it enters the public domain, through no fault of the Institution, Investigator or any other individual participating in the Trial. Confidentiality obligations set out above shall not apply in case the disclosure of any such confidential information is in compliance of any law in force or consequent upon any direction of any governmental, statutory authority or a court of law or tribunal. This clause shall survive the termination of this Agreement.

b. In accordance with Clause 9, Institution and Investigator will obtain the consent authorization document of each Trial subject to the holding and transfer of their data to countries other than their own, to countries that may not have the same level of data protection, as within their own country.

c. The Sponsor will process, use or transfer any personal information received from either the Trial subject or any individual involved in the Trial in accordance with any applicable data protection laws. Sponsor shall require that any party to whom sponsor discloses Health Information ("Recipient") agrees to use and disclose the Health Information only as permitted in the Authorization Documents and in accordance with all applicable laws and regulations. The Authorization Documents will not authorize the sponsor or any Recipient to use Health Information to recruit research subjects to additional studies, to advertise additional studies or products or to perform marketing or marketing research.

d. All documents, Protocols, data, know-how, methods, operations, formulas, confidential information and materials provided to the Institution and/or Investigator pursuant to this Agreement are and shall remain Sponsor's property. The Institution and the Investigator agree that case report forms or CRFs, the Final Report and other results of the Trial, if any, together with any patents, patent applications and other like forms of protection, database rights, registered and unregistered design rights, copyrights and rights in unpatented technical, intellectual property rights and other information not in the public domain which may subsist in any part of the world ("Intellectual Property") subsisting in or capable of subsisting in or otherwise protecting or capable of protecting any of the foregoing matters shall also be owned by Sponsor. The Institution and the Investigator shall ensure that all individuals working on the Trial, including the Investigator have assigned to Sponsor or have a legal obligation to disclose and assign to Sponsor all their rights to any of the Intellectual Property.

e. Neither CRO nor Sponsor shall transfer to Institution and Investigator by operation of this

Agreement or otherwise any intellectual property (including the Intellectual Property) or other proprietary right of Sponsor.

f. It is expressly agreed that all other discoveries and inventions under this Agreement ("Other Inventions") that are developed solely by Investigator /Institution shall be owned by Institution.

g. Upon completion / termination of the Trial, all such materials, information and data (including the confidential information and Intellectual Property) in the Institution's and Investigator's custody or control, except as required for archiving under ICH GCP and applicable national and local regulations, shall be promptly delivered to CRO.

7. Ethics Committee Approval

Written approval for the conduct of the Trial, the terms of the Protocol and the informed consent documents must be obtained from a properly constituted Ethics Committee or EC according to ICH GCP, National Ethical Guidelines for Biomedical and Health Research involving Human Participants, 2017 Rule 122DAA New Drugs and Clinical Trials Rules, 2019(section 3.0), as applicable, prior to the commencement of the Trial at the Site. Institution and Investigator shall be responsible for obtaining EC approval of such documents (and any amendments thereto). A copy of such approval, clearly identifying the documents reviewed and approved (including version dates/numbers) along with other such documents required by Rule 122DAA New Drugs and Clinical Trials Rules, 2019 must be obtained and copies provided to all parties before release of the Trial Supplies will be permitted at the Site. Such approval must indicate the date approval was given and the name and signature of the chairperson/or authorised personnel. The names, occupations and institutional affiliations of the EC must also be submitted to CRO, along with a statement to the effect that they are organised and operate according to ICH GCP and/or the applicable national laws and regulations. Institution and Investigator agree to submit Trial reports to the EC regularly and at least annually.

8. Adverse Event Reporting and Trial Subject Compensation

a. By way of background and as defined by ICH-GCP; an adverse event is any untoward medical occurrence in a volunteer administered a pharmaceutical product and which does not necessarily have a causal relationship with this treatment ("AE"). An AE can therefore be any unfavourable and unintended sign (including an abnormal laboratory finding), symptom, or disease temporally associated with the use of a medicinal (investigational) product, whether or not related to the Trial supplies. A serious adverse event is any untoward medical occurrence that at any dose: results in death, is life-threatening, requires in-patient hospitalization or prolongation of existing hospitalization, results in persistent or significant disability/incapacity, or is a congenital anomaly/birth defect(an "SAE").

b. The investigator shall ensure that all Serious Adverse Events are reported, analysed and managed in accordance with the applicable Rules and Regulations at the time of execution of this Clinical Trial Agreement, and in accordance with the applicable Standard Operating Procedures and protocol requirements, while ensuring that the rights, safety and well-being of trial participants are

protected.

c. If a Trial subject is admitted for a SAE or develops an AE related to the Protocol or the Trial Supplies, Sponsor shall provide full cooperation in handling medical expense management and Financial Compensation as per the Rule 122DAA New Drugs and Clinical Trials Rules, 2019 Section: 3.5 (Third Schedule).

9. Monitoring

a) The Trial will be monitored by CRO and also may be by sponsor representative at few sites. Institution and Investigator must allow a reasonable amount of time to be set aside at each monitoring visit for discussions and to make corrections to the CRFs. The monitor will give as much notice as possible when scheduling visits and these will occur at a mutually convenient time. In accordance with the Rule 122DAA New Drugs and Clinical Trials Rules, 2019, the Investigator and the Institution will provide direct and prompt access to source data and documents for Trial related monitoring, audits, EC review, and regulatory inspection.

b) If any source data is kept on computer files only, for the purpose of source data verification, the Institution and the Investigator agree to make a print out of all volunteer data relevant to the Trial. These print-outs will be dated and signed and retained as source documents. This includes relevant history information and all data obtained during the Trial.

c) Volunteer confidentiality will be respected by all the parties as required by local law, and neither the Institution nor the Investigator will remove (or permit to be removed) any Trial documents bearing Trial subject names from the Site. Trial subjects will be identified by code numbers and initials.

10. Volunteer Consent

Institution and Investigator shall also be responsible for obtaining an informed consent /authorization document signed by or on behalf of each Trial subject. The informed consent document shall be approved by Sponsor and the EC, prior to the Trial subject's participation in the Trial.

11. Audits and Inspection

a. This Trial may be audited by the Quality Assurance Department of CRO and/or by Sponsor, or inspected by governmental or regulatory bodies, in order to document the authenticity of recorded data and Protocol adherence. Both the Institution and the Investigator agree to cooperate and procure cooperation with such audits and inspections and following written notification, to allow an independent audit of all Trial documentation and processes.

b. Should the Sponsor or its agents or affiliates, including CRO ever become the subject of an audit or investigation by a governmental authority, including under any applicable anti-corruption laws and regulations, Institution and Investigator agree to cooperate fully and procure cooperation with such audit and inspection including providing any information and

records related to trial that the Institution or Investigator are required to disclose will be disclosed as part of such an audit.

12.Record Retention

All documentation, records and correspondence relating to this Trial need to be maintained by site till closeouts and then later CRO will archive the documents with central archival. Sponsor must be informed in writing of any change of address or relocation of the Trial files during this period.

13.Publications

Publication, presentation or use ("Publication") of the methods, any scientific or other data related to or obtained as the result of the Trial are not permitted until the multi-centre clinical study has been completed in its entirety at all sites and then such Publication shall be subject to the written approval of the Sponsor.

14.Independent Contractor

In their activities in connection with the Trial, each of the Institution and the Investigator agree that they will act as an independent contractor, without the capacity to act on behalf of or legally bind CRO or Sponsor, and not as an agent, partner, joint venture or employee of Sponsor or CRO.

15. Insurance /Indemnity, Product liability & Subject Injury

a) The Institution and/or the Investigator will promptly notify the Sponsor and CRO in writing of any claim, AE or other injury actually or allegedly due to this Trial (in accordance with Clause 7) and will allow the Sponsor to deal with any such claim (including settlement negotiations), and shall cooperate fully with the Sponsor in its handling of any such claim. [Sponsor has agreed to indemnify the Institution and the Investigator from and against all direct losses arising out of claims that result from use of the Trial Supplies in compliance with the Protocol, during the course of the Trial].

b) Each of the Institution and the Investigator hereby agrees that neither Sponsor nor CRO shall be responsible for, and that they each undertake to indemnify and hold CRO and Sponsor, harmless for all losses, damages and liabilities (including reasonable legal fees) resulting from their negligence, wilful misconduct or other actions or omissions.

c) 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 Ethics Committee/Institutional Review Boards, and others holding appointments within those institutions and their respective heirs, successors, and assigns, from any liability, loss, or damage they may suffer as a result of claims or judgments that arise from the participation in and/or performance of the subject Study. Sponsor shall employ attorneys of its own selection and will be responsible for all expenses that result from employing a vigorous, diligent

defence of Invigilator/Institution, regardless of whether any claims are rightfully or wrongfully brought or filed.

d) Sponsor through CRO warrants that it has insurance for the Trial Subjects included in the Trial in place at Trial start as per the Applicable Laws. The Institution warrants that it has appropriate and adequate professional indemnity insurance to cover claims or damages for which it shall be liable under this Agreement. The Principal Investigator warrants that he has appropriate medical liability insurance. All the parties shall provide each other evidence of its insurance showing that such insurance is in place.

e) The insurance coverage obtained by the Sponsor does not relieve the Investigator, Institution and their employees and agents of their obligation to be responsible for their own negligence, wilful misconduct or other actions or omissions or their obligation to compensate and/or obtain their own insurance coverage in accordance with applicable laws and regulations.

f) The Sponsor and CRO will not be liable for and are not a party to unauthorized representations or warranties made by the Institution or the Investigator or their agents relating to the Trial drug.

g) Sponsor agrees that the Subjects shall be entitled to financial compensation as well as reimbursement of reasonable and necessary medical expenses from the sponsor in case of Subject injury (as Adverse Event or Serious Adverse Event) or death during the conduct of Study in accordance with New Drugs and Clinical Trials Rules, 2019 & It's amendments as may be amended from time to time. Further, in case the injury occurring to the subject during the Clinical Trial or even thereafter as a result of this trial, the subject or the subject's nominee(s) shall also be entitled for financial compensation from the sponsor and the financial compensation will be over and above any expenses incurred on the medical management of such subject.

16. Termination

(i) Sponsor may terminate the Trial prior to its completion by 15 days written notice without cause, or immediately upon written notification for any of the following reasons:

a) if available data indicates that it is, in their sole opinion, not safe to continue to administer the Trial drug or Trial Supplies to volunteers;
b) if the Institution or the Investigator is in breach of any term of this agreement (including but not limited to any warranty or undertaking);
c) if CRO's agreement with Sponsor is terminated or expires;
d) by agreement, in writing, between CRO and the Institution and the Investigator;
e) if the entry of valid Trial subjects into the Trial is too slow to meet the agreed time scheduled;
f) if adherence to the Protocol is poor or data recording is materially inaccurate or incomplete; or
g) if overall Trial enrolment has been met even if enrolment in terms of this Agreement has not been completed.

(ii) The institution shall have the right to terminate the conduct of the Trial upon 15 days written notice if necessary to protect the wellbeing of Trial Subjects.

(iii) It, though no fault of Investigation, the Study is never initiated because of Ethics Committee disapproval, this Agreement will terminate immediately.

Swami Rama Himalayan University
Registrar

(iv) The principal Investigator reserves the right to terminate the Study immediately upon notification to the Sponsor, if requested to do so by the responsible Ethics Committee or if such termination is required to protect the health of Study subjects.

(v) Either Party may terminate this Agreement with immediate effect by written notice to the other in the event that-

(a) the other Party commits a material breach of this Agreement which (if remediable) is not remedied within thirty (30) days of a written notice from the non-defaulting party; or

(b) the other party becomes insolvent.

Any violation of the good clinical practices, the Applicable Anti-Corruption Legislations, or data protection provisions under the Applicable Laws shall be deemed to be a material breach of this Agreement.

Upon termination Sponsor will reimburse the Institution (once received the required amount from the sponsor) for actual and necessary expenses incurred or committed to the date of notice of termination. CRO will further cooperate with the Institution and the Investigator to ensure closure of the Trial on a medically and ethically acceptable basis. In the event of termination, the Institution and the Investigator will be obliged to notify the EC.

17.Debarment & Disqualification

The Institution and the Investigator hereby certify that neither of them have been disbarred or disqualified from carrying out clinical trials and that to the best of their knowledge neither have any of the individuals involved in the administration of the services of the Trial. In the event that the Institution or the Investigator becomes aware of the debarment, threatened debarment, disqualification or threatened disqualification, or the conduct of activity that could lead to any of the aforementioned disqualification or debarment actions, of or by any individual, they will immediately notify CRO.

18.Publicity

CRO and Sponsor may use, refer to and disseminate reprints of scientific, medical and other published articles which disclose the name of the Institution and/or the Investigator consistent with applicable copyright laws, provided such use does not constitute an endorsement of any commercial product or service by the Institution or the Investigator. Except, where discloser required for performing under this agreement, neither the Institution nor the Investigator shall disclose the existence of this Agreement or its association with CRO or Sponsor or use the name of Sponsor or CRO in any press release, article or other method of communication with the general public, without the express prior written approval of the party whose name is the subject of the potential disclosure. Both CRO and Sponsor may use Institution and Investigator contact details and Trial status in Trial specific newsletters and on the World Wide Web for the purpose of conducting this Trial. Newsletters (which may be distributed to all participating sites) and

postings to the web are for the purpose of providing information to potential volunteers regarding the Trial, giving them the ability to contact participating sites.

19. Trial Supplies

The Investigator and the Institution shall use the Trial drug and any placebo, comparator, adjunctive use or other products provided in connection with the Trial (together with Trial drug, "Trial Supplies"), solely for the purpose of properly completing the Trial and shall maintain all Trial Supplies in a locked, secured area at all times in accordance with Sponsor's instructions and/or the Protocol. Upon completion or termination of the Trial at the Institution, the Institution shall promptly make available for collection by Sponsor, CRO or their designees, all unused Trial Supplies, Intellectual Property, Property (as defined below) and materials and copies of confidential information. Site may retain, for a maximum period of 2 (two) years, a single archival copy of the confidential information for the sole purpose of determining the scope of its obligations incurred under this Agreement and to the extent required by applicable laws and regulations.

20. Warranties, Terms and Representations

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) Institution and Investigator acknowledge and agree that fabrication, falsification or alteration by institution, investigator or any employees or agents of the institution of any trial subject data or other information provided by institution or investigator pursuant to this agreement may result in criminal or civil actions and sanctions against institution, investigator to CRO and the sponsor.

c) Institution and Investigator acknowledge and agree that there are anti-corruption laws to which Sponsor is subject that prohibit the payment or offering of anything of value to a government employee or official for the purpose of: inducing or influencing any governmental act or decision affecting the Sponsor, to help Sponsor obtain or retain any business, to serve as an inducement for approval, reimbursement, prescription, or purchase of any Sponsor product (including, the Trial drug), to influence the outcome of any clinical trial (including, the Trial); or to otherwise improperly benefit the Sponsor's business activities. Institution and Investigator each agree to refrain from any activity in connection with this Agreement or the Trial that would constitute a violation by Institution, Investigator, CRO or Sponsor of such laws.

d) Institution and Investigator each acknowledge and agree that the compensation provided hereunder constitutes fair market value for the performance of the Trial and that no part of the payments hereunder shall be paid to or shared with, directly or indirectly with any government or political party official (including as applicable the Investigator or sub-investigator).

e) The Institution and Investigator each acknowledge and agree that they have the education,

experience, capabilities, adequate volunteer population, adequate personnel, equipment and other resources to conduct the Trial in a professional and competent manner, and that they are fully aware of applicable regulations; furthermore, they agree that they will not participate in any other Trial that by its nature will prevent them from fulfilling their obligations in the Trial hereunder.

f) Sponsor warrants to Institution that it shall have and maintain appropriate/applicable licences, approvals, permits, certifications and the like necessary to lawfully perform its obligations under this Agreement. In particular, the Sponsor shall comply with all reporting rules, as per the applicable regulatory agency, that require it to inform Institution and/or Principal Investigator of any serious and adverse experience associated with the Study Drug or device.

21.Financial Disclosure

The Institution, Investigators and sub-investigators will complete a financial disclosure form (if applicable), disclosing any compensation payable to and financial interests held by the Investigator, sub-investigator or their spouse and/or dependants and shall maintain the form for one (1) year after completion of the Trial.

22.Miscellaneous

a) This Agreement supersedes all prior written and oral agreements and representation between the parties with respect to the subject matter hereof. All obligations contained herein as to which performance is required after termination of the Agreement shall survive termination. This Agreement may not be assigned or transferred by the Institution or the Investigator without the prior written consent of Sponsor. Sponsor may assign or transfer this Agreement upon written notice to the Institution or the Investigator. In the event Sponsor assigns or transfers this Agreement to a third party who will assume all obligations hereunder, the Institution and the Investigator shall each release and forever discharge Sponsor and its subsidiaries and affiliates from any and all liabilities and obligations of Sponsor arising under the Agreement from and after the effective date of such assignment.

b) In case of any dispute or difference between parties hereto regarding the construction, meaning, effect or obligation of the parties hereto under this Agreement, the same shall be settled by amicable consultation. If the said dispute or difference cannot be settled by amicable consultation within 30 days, it will be referred to arbitration by a sole arbitrator mutually appointed by the Parties, as per the provisions of the Arbitration and Conciliation Act, 1996 or any re-enactment or modification thereof. In the circumstance 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 shall be in English language and the venue of arbitration shall be Dehradun, Uttarakhand, India. It is expressly agreed that the arbitral award shall be final and binding upon both the Parties hereto.

c) The following provisions shall survive the termination or expiry of this Agreement: Intellectual Property, Publication, Confidentiality, Data Privacy Insurance /Indemnity, Product liability &

Subject Injury and Adverse Event Reporting & Trial Subject Compensation as well as any other provisions which by their terms are understood to survive the termination or expiry of this Agreement, including compliance with Applicable Laws.

d) If any provision of this Agreement conflicts with the law under which this Agreement is to be construed, or if any such provision is held invalid by a court, such provision shall be deemed to be restated to reflect as nearly as possible the original intentions of the parties in accordance with applicable law and the remainder of this Agreement shall remain in full force and effect.

e) This Agreement shall be binding upon the parties, their heirs, successors, and permitted assigns.

f) Waiver or forbearance by either party with respect to a breach of any provision of this Agreement or any applicable law shall not be deemed to constitute a waiver with respect to any subsequent breach of any provision hereof.

g) Any notice required or permitted to be given hereunder by either party hereto shall be in writing and shall be deemed given on the date received if delivered personally, by recognized overnight courier, or by facsimile, or five (5) days after the date postmarked if sent by registered or certified mail, return receipt requested postage prepaid, to the following address:

If to CRO:
Mr. D. T. Arasu
iDD Research Solutions Pvt. Ltd.
First Floor,
12/A , 19th Main Road,
3rd Sector HSR Layout,
Bangalore-560102, Karnataka.
India.

If to Investigator:
Dr. Nand Kishore,
Himalayan Institute of Medical Sciences,
Swami Rama Himalayan University Campus,
Jolly Grant,
Dehradun-248140, Uttarakhand
India.

If to Institution:
Himalayan Institute of Medical Sciences,
Swami Rama Himalayan University Campus,
Jolly Grant,
Dehradun-248140, Uttarakhand
India.

Any party may change its notice address and contact person by giving notice of same in the manner herein provided.

23 Agreement

The fee quoted in the budget schedule appended is exclusive of any taxes, if applicable, chargeable thereon. It is the Institution and Investigator's responsibility to ensure that the hospital management is made aware of their participation in this Trial and approval is obtained prior to commencing the Trial.

24 Right to Information

24.1 The parties agree that the Institution may be subject to right to information act("RTI").

24.2 If the Institution receives a request under RTI to disclose any information or any confidential information of Sponsor or CRO, it will notify CRO and Sponsor as soon as possible, in any event, not later than three (3) working days after receiving the request and will consult with the Sponsor in accordance with all applicable guidance.

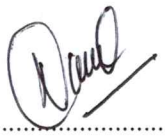
25 Governing law

This Agreement shall be governed by and construed in accordance to the Laws of India. However, the final jurisdiction shall lie with the courts of Dehradun, Uttarakhand, India. Each of the Parties hereby expressly submits to the jurisdiction of the courts of Dehradun, Uttarakhand, India.

We hereby agree to the conditions in this agreement:

Swami Rama Himalayan University
Registrar

Signed for and on behalf of the Investigator:



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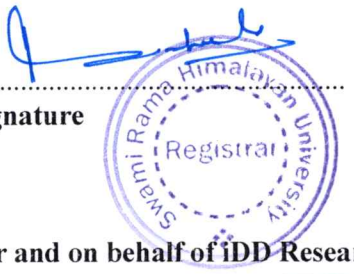
Investigator's signature **Date**

Signed for and on behalf of the Institution :



..... 12/12/2023

Signature **Date**

Signed for and on behalf of iDD Research Solutions Pvt. Ltd.

For iDD Research Solutions Pvt. Ltd.

Director

..... 06-NOV-2023

Signature **Date**

Authorised Signatory CRO

APPENDIX A

PAYMENT TERMS AND BUDGET SCHEDULE

1. Payment Terms:

   a) **Payment (Appendix B)** will be to institution for every complete and evaluable volunteer as defined below.
   b) All invoices will be raised by Institution/ Investigator representative in the currency specified in this Appendix B.
   c) A complete and evaluable volunteer is defined as follows:
      - All procedures must be performed according to the Protocol and applicable guidelines and regulations.
      - A volunteer will only be included according to the inclusion/exclusion criteria.
      - All data are documented accurately, completely.
   d) All payments will be on a *pro rata* basis. For volunteers who do not complete the Trial, the payment schedule will be evaluated according to the number of visits performed.
   e) Laboratory costs as well as the protocol specific tests, Coordinator costs and other expenses will be as per appendix B.

Should the Trial terminate prematurely, any payments made by IDD exceeding the amount actually earned will be promptly refunded to IDD. In such an event, the amount earned shall be determined in accordance with criteria as stated above. All refunds to IDD will be made by cheque payable to iDD Research Solutions Pvt. Ltd. and sent to the following address,

iDD Research Solutions Pvt. Ltd.
First Floor, 12/A , 19th Main Road,
3rd Sector HSR Layout,
Bangalore-560102, Karnataka, India,

Payments will only be made to the party or parties identified in the Payment Invoice (Appendix C), any deviation from this will need to be agreed by the parties in writing.

Swami Rama Himalayan University
Registrar

APPENDIX B

INVESTIGATOR FEE

Payment Break Up

Study activities and procedures	**Planned cost**
Investigator Payments+Study Teams	10000 per patient (25 patient is a target)
Lab Investigations cost per subject or total	On Actuals
IEC Fee	On Actuals

Investigator Payment Breakup	
Upon achievement of Day1/ Screening/ Baseline	2500/- Per Patient
Upon achievement of Day 4	2500/- Per Patient
Upon achievement of Day5/Day 7	2500/- Per Patient
Upon achievement of follow-up visit day 28	2500/- Per Patient
Total	10000/- Per Patient

* Total study grant for (Investigator) 25 patients is INR– 2,50,000/-

Note: Payments will be released upon the retrieval of CRF.

Payments will be released 30 days from the date of invoice raised.

Site agreed upon the Central Archival.

for iDD Research Solutions Pvt. Ltd.

Director

Swami Rama Himalayan University

Registrar

APPENDIX C

PAYMENT INVOICE

Protocol number: GB_LAB_001_21
Study Title: A post marketing surveillance study to assess safety and tolerability of Liposomal Amphotericin B Injection (GUFISOME) in patients with Invasive Fungal Infection who are refractory to or intolerant of conventional Amphotericin B therapy.

Investigator Name: Dr. Nand Kishore

Institution Name: Himalayan Institute of Medical Sciences

S.No.	Description	Amount
1 2 3	**Payee name:** **Pan number:** **Period:** From To	
	Total	
Rupees in words:		

Authorized Signatory

Addendum

This is additional information for the CTA for the Himalayan Institute of Medical Sciences, Swami Rama Himalayan University Campus, Jolly Grant, Dehradun-248140, Uttarakhand India.

Payment Break Up

Study activities and procedures	**Planned cost**
Investigator Payments + HOI	10000 per patient (25 patient is a target)
HOI Fee (30%)	3000/- Per Patient
PI Fee (70%)	7000/- Per Patient
Lab Investigations cost per subject or total	On Actuals
IEC Fee	On Actuals

HOI & Investigator Payment Breakup	
Upon achievement of Day1/ Screening/ Baseline	HOI (Rs 500/-) + PI (Rs 1000/-) Per Patient
Upon achievement of Day 4	HOI (Rs 500/-) + PI (Rs 2000/-) Per Patient
Upon achievement of Day5/Day 7	HOI (Rs 1000/-) + PI (Rs 2000/-) Per Patient
Upon achievement of follow-up visit day 28	HOI (Rs 1000/-) + PI (Rs 2000/-) Per Patient
Total	10000/- Per Patient

* Total study grant for (Investigator) 25 patients is INR– 2,50,000/-

Note: Payments will be released upon the retrieval of CRF.

Payments will be released 30 days from the date of invoice raised.

Site agreed for the Central Archival.

Swami Rama Himalayan University Registrar

Signed for and on behalf of the Investigator:

.....

Investigator's signature

05/12/23

.....

Date

Signed for and on behalf of the Institution :

.....

Signature

Swami Rama Himalayan University Registrar

12/12/2023

.....

Date

Signed for and on behalf of iDD Research Solutions Pvt. Ltd.

.....

Signature

Authorised Signatory CRO

.....

Date

iDD Research Solutions Pvt Ltd