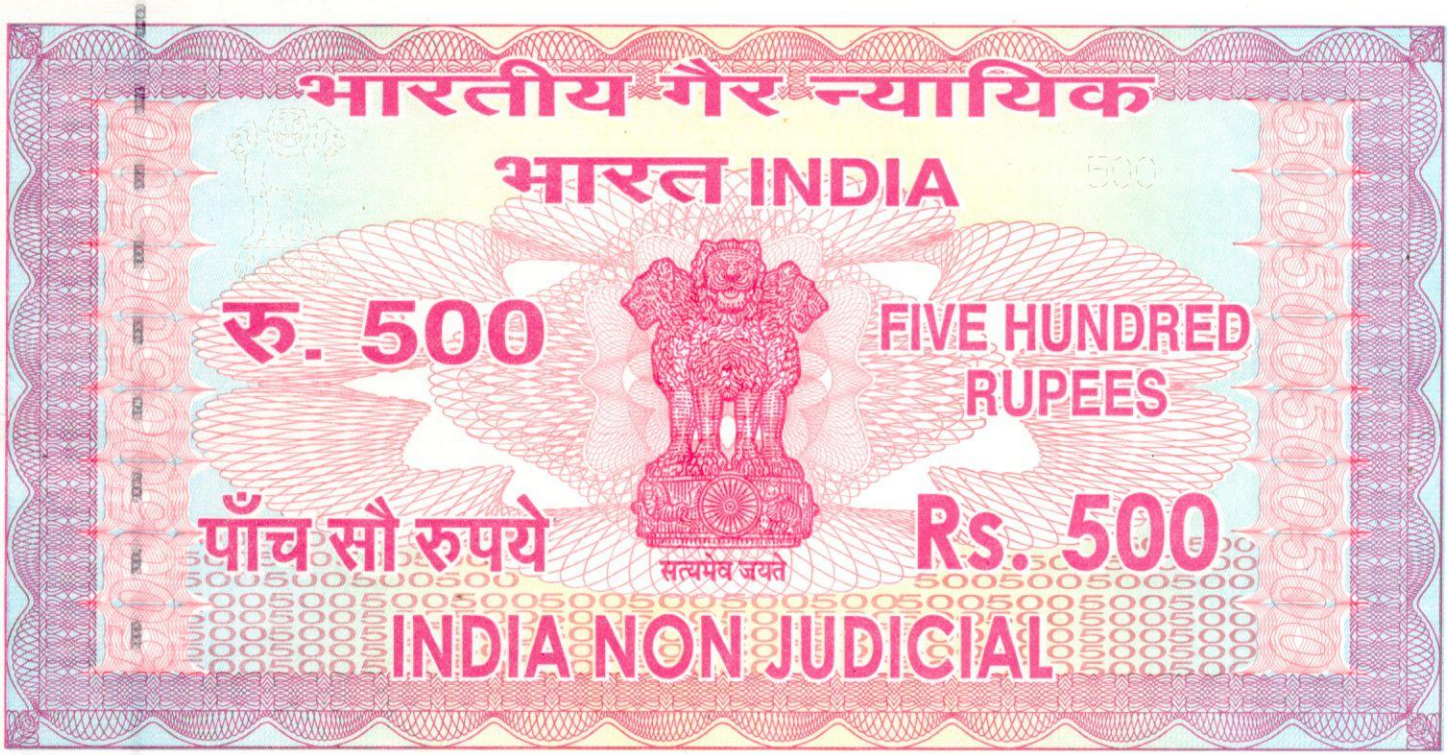

महाराष्ट्र MAHARASHTRA ◐ 2023 ◐ CC 869886

अनु.क्र. 73301 दि. 23 OCT 2023
मु.शु.रक्कम- 500
दस्ताचा प्रकार- AGREEMENT
दस्त नोंदणी करणार आहेत का? होय/नाही.-
मिळकतीचे वर्णन-
मुद्रांक विक्रत घेणाऱ्याचे नांव- Prorelix Services LLP
पत्ता- 102 A/B, Park Plaza, Karvenagar, Pune 52
दुसऱ्या पक्षकाराचे नांव- Index medical college Hospital & Research center
हस्ते व्यवतीचे नांव व पत्ता- Dnyaneshwar sutar, Shivane Pune

वरिष्ठ कोषागार अधिकारी पुणे
16 OCT 2023
प्रथम मुद्रांक लिपीक कोषागार पुणे करिता.

नितीन एन. गांधी (परवाना नं.२२०१०५४)
शॉप नं.२१, केदार एम्पायर, कर्वेरोड, पुणे-३८ फोन-२५४६३४८५ हस्ते/मुद्रांक विक्रेत घेणाऱ्याची सही

मुद्रांक खरेदी केल्यापासून ६ महिन्यात वापरणे बंधनकारक आहे
या कारणासाठी जोनी मुद्रांक खरेदी केला त्यांनी त्याच कारणासाठी वापरा

CLINICAL TRIAL SERVICES AGREEMENT

This Agreement is made and entered into this 23rd day of October 2023 by and between:

Dr. Sudhir Mourya
Head of Department
Index Medical College, Hospital and Research Center
Nemawar Rd, village, near Khudel, post Bavlia, Indore, Madhya Pradesh 452016.
Hereinafter "Principle Investigator"

Dr. G.S.Patel
Dean
Index Medical College, Hospital and Research Center
Nemawar Rd, village, near Khudel, post Bavlia, Indore, Madhya Pradesh 452016.
Hereinafter "INSTITUTION",

And **ProRelix Services LLP**
102 A/B, 1st Floor, Park Plaza,
Near State Bank Colony,
Karve Nagar,
Pune - 411052.
Hereinafter "CRO"

For study titled: **"A Multicenter, Randomized, Double Blind, Placebo Controlled Study to Evaluate Safety and Efficacy of Orally administered NUV001 nutraceutical supplement in Sickle Cell Disease (SCD) patients."**

WHEREAS CRO is engaged in the business of clinical trials management as a Contract Research Organization and intends to carry out the NUV001 ("The Investigational Product") Clinical Study (Hereinafter "The Study" / "Clinical trial") and is acting on behalf of LGD-SARL - NUVAMID (Hereafter "SPONSOR") and; WHEREAS, the CRO has represented that it has entered into an agreement with the SPONSOR dated where by the terms and conditions governing the conduct of the clinical trial at the INSTITUTION have been incorporated.

Subject to the condition of obtaining the pertinent ethics committee approval and the parties intend to participate in the Study by rendering their services and agree to the following:

1. **INVESTIGATIONAL PRODUCT:** RBCs from individuals with sickle cell disease are more susceptible to oxidant damage. Because key antioxidant defense reactions are linked to the pyridine nucleotides nicotinamide adenine dinucleotide (NAD) and nicotinamide adenine dinucleotide phosphate (NADP).Sickle RBCs have a significant decrease in the NADH/[NAD+ + NADH] ratio compared with normal RBCs (P less than .00005). Interestingly, sickle RBCs also have a significant increase in total NAD content compared with normal RBCs (P less than .00005). In contrast, although sickle RBCs have a significant increase in the total NADP content compared with normal RBCs (P less than .00005), sickle RBCs had no significant alteration in the NADPH/[NADP+ + NADPH] ratio. High reticulocyte controls demonstrated that these changes were not related to cell age. Thus, sickle RBCs have a decrease in NAD redox potential that may be a reflection of their increased oxidant sensitivity. The changes in these pyridine nucleotides may have further metabolic consequences for the sickle erythrocyte.

   Hence the current study was designed to evaluate the safety and efficacy of orally administered NUV001 nutraceutical supplement (Nicotinamide mononucleotide NMN) in SCD patients.

2. **INSTITUTION:** The CRO have approached the Principal Investigator / Study site on behalf of the SPONSOR, as the SPONSOR desires the Principal Investigator/ Study site to perform the study in regards to the said Investigational Product in accordance with the following standards:

(a) The current World Medical Association Declaration of Helsinki titled "Ethical Principles for Medical Research involving Human Patients"

(b) The current ICH Harmonized Tripartite Guideline for Good clinical Practice 2019 (ICHE6R2);

(c) The current Indian Ministry of health and Family Welfare Guidelines for good clinical practice titled, "Good Clinical Practices for Clinical Research in India";

(d) The current Indian Council of Medical Research on Human Patients;

(e) The written requirements of all reviewing independent ethics committees and institutional review boards (collectively, the Independent Ethics Committees);

(f) The Principal Investigator requirements;

(g) All policies and procedures of the Principal Investigator/Study site;

(h) All current and applicable permission, licenses, approvals, federal wide assurance and certifications and (1) all current and applicable laws and regulations (such as standards set forth inSections2(a) – (i) collectively referred to hereafter as the Standards) and;

(i) In accordance with the final protocol, patient information sheet, informed consent documents and Case report forms for the above-referenced clinical study of which is attached here to, which attachment shall be replaced in the final version and all amended versions, if any. It is understood and agreed that, in the event of a conflict among any of the standards, the most stringent standard shall apply.

(j) Per patient per bed charges are not applicable for this study.

(k) Principal Investigator / Study site shall be responsible for providing the hospital space, nursing care and general support services for the patients included in this study, free of cost, including ICU care, if required.

3. PERFORMANCE:

a) Protocol and Standards: The Principal investigator/ Study site, hereby confirm that they have read and understood the Clinical Trial Protocol for the Study to be conducted in Sickle Cell patients, and further confirm that their research team is properly trained concerning the Clinical Trial Protocol and Standards. The Principal Investigator/ Study site agree to the final Clinical Trial Protocol and to perform the study in strict accordance with this Agreement.

b) Subcontracting: Services of Principal Investigator/Study site: The Principal Investigator/Study site shall not subcontract the performance of any or all of its obligations under this Agreement to any third party (including to any affiliate). The services of the Principal Investigator are considered essential for the performance of this Agreement. If for any reason the Principal Investigator becomes unavailable or otherwise unable to supervise and direct the activities under this Agreement, Principal Investigator/Study site shall promptly notify the CRO/SPONSOR. If a mutually acceptable successor is not promptly identified, this Agreement may be terminated by the CRO/Sponsor.

c) Study Duration: It is anticipated that the Clinical Study will commence upon execution of this Agreement, after the study initiation date and subject to clearance to EC and all necessary requirements of the site.

d) Recruitment: The Principal Investigator/ Study site understands and agrees that the CRO/SPONSOR requires minimum of 20 evaluable patients at the conclusion of the Study from this site, however recruitment is competitive, hence it will be necessary for the INSTITUTION to enroll and complete as many patients as possible who satisfy all enrollment criteria specified in the Clinical Trial Protocol, within a period of 60 days after the ethics committee approval for the study and further sponsor approval for the commencement of the study.

e) Confidentiality:

Definition: During the term of this agreement, the Principal Investigator may have access to information, know-how, knowledge and data in oral, written, electronic, graphic or other tangible form, confidential or proprietary to SPONSOR or to SPONSOR's other collaborators and is, therefore of a confidential nature (confidential information). Confidential information shall include the Clinical Trial Protocol, SPONSOR's Investigator's Brochure concerning the Investigational Product data, all Study Data, all documents maintained in the Clinical Trial Record Binder (site documentation), any other data emerging out of the protocol, any other information supplied by SPONSOR/CRO during the course of the study and clinical development plan, except the information already existing in the public domain, and all results and reports obtained, collected, conceived, processed and developed pursuant to this Agreement.

i. Use: The Principal Investigator shall hold all confidential information and shall disclose confidential information only to its Co-Investigators, hospital staff and employees who have a need to know such confidential information for the purpose of this agreement and

Who agree in writing to keep such confidential information, confidential under terms substantially similar to those set forth herein. The Principal Investigator shall use confidential information for the sole purpose of providing services under this Agreement and shall not use confidential information for own benefit at any time. No right or license under any patent application, trade secret or other proprietary right now or hereafter owned or controlled by the SPONSOR or other collaborators is granted to the Principal Investigator from the provision of confidential information hereunder. The Principal Investigator shall comply with the Study Data Confidentiality conditions.

ii. Provision to CRO/SPONSOR: The Principal Investigator agrees that, at any time upon CRO/SPONSOR's request, it shall promptly provide to the CRO/SPONSOR respectively, copies of all Confidential Information under this Agreement. The Principal Investigator further agrees that upon any termination or expiration of this Agreement, it shall at CRO/SPONSOR's discretion ,return to the CRO/SPONSOR or destroy all copies of all Confidential Information; however that the Principal Investigator may retain two (2) archival copies, with obligation to maintain the confidentiality of such confidential information for the period of 7.5 years.

f) Work Product:

i. Definition: The Parties agree that all work performed by the Principal Investigator hereunder including, without limitation, all study data, results, reports, inventions, discoveries, new uses or know-how obtained, collected, conceived, processed, developed, improved or reduced to practice by Principal Investigator or the other hospital staff or employees pursuant to this Agreement (collectively, work product) shall be the property of the SPONSOR.

ii. Disclosure, Assignment and Provision to CRO/SPONSOR: The parties agree that the Principal Investigator shall promptly disclose to the CRO/SPONSOR any and all work related to the product comprising inventions, discoveries, new uses or know-how obtained. As per the agreement, the CRO/SPONSOR can review and obtain copies of all work related to the product including and without limitation, all study data, in an agreed–upon format and with a complete glossary of terms used for such data.

iii. Materials: The study medication, blood samples from patients under the study and all other tangible material provided to or obtained by the Principal Investigator under this Agreement (collectively the Materials) shall be the property of the SPONSOR and/or SPONSOR's other collaborators (other than the Principal Investigator). The Principal Investigator shall use the Materials for the sole purpose of providing services under this agreement and shall not use the materials for its own benefit at any time. No right or license, any patent, patent application, trade secret or other proprietary right now or hereafter owned or controlled by SPONSOR or SPONSOR's other collaborators is granted to the

Principal Investigator from the provision of materials hereunder. Upon any remaining Investigational Product and other Materials received or obtained hereunder in accordance with the Protocol, standards and the directions of CRO/SPONSOR.

g) : The Principal Investigator/Study site shall be responsible for safeguarding the rights and welfare of patients in the study. The Principal Investigator shall ensure (i) the rights and welfare of each such patient are protected, (ii) informed consent of each such patient is freely and knowledgeably given: (A) to participate in the study and (B) for the collection by, processing by and disclosure to and between the CRO representatives of SPONSOR, Principal Investigators and Researcher, Study Monitors, Study Laboratory Personnel, Study Data Analysts, members of the Independent Ethics Committees and representatives of governmental and inter-governmental agencies in India; (iii) the balance between risk and potential benefit from participating in the study has been assessed and deemed acceptable; and (iv) the Principal Investigator/Study site has made appropriate arrangements to eliminate, mitigate and/or compensate for the consequences to such patients and their families in the case of any death, injury or illness for which the Principal Investigator/Study site has agreed to assume liability, in accordance with section 12 herein. Such arrangements shall include medical treatment and financial relief.

h) Ethical Approval: The Principal Investigator/Study site shall petition for written certification of ethical approval of the Study from its Independent Ethics Committee. The Principal Investigator/Study site shall keep the CRO/SPONSOR fully advised of the progress of such submission and shall upon request, provide the CRO/SPONSOR with all correspondence relating to such submission. The Principal Investigator/Study site shall obtain such certification prior to screening any patients for the Study, annually after obtaining such certification, and prior to implementing any changes to the Clinical Trial Protocol. Upon receipt of such certification, the Principal Investigator/Study site shall promptly provide a copy to the CRO/SPONSOR.

i) Case Report Form Handling: The Principal Investigator shall be responsible for providing correct Electronic Case Report Forms ("e-CRF") according to the following:

i. The main objective of the e-CRF is to obtain those data required by the Protocol in a complete, accurate, legible and timely fashion. The data in the e-CRF must be consistent with the relevant source documents, and they must be suitable for submission to authorities.

ii. The data recorded in the course of the Study shall be documented in the e-CRFs as necessary. They will then be forwarded to CRO/SPONSOR for data management and biometric analysis.

iii. The data in the e-CRF shall be recorded, evaluated, and stored in anonymous form in accordance with data-protection regulations within 48 hours of obtaining the data from the patient. The Principal Investigator/Study site shall ensure that patient names are not mentioned on any document, neither e-CRFs nor other documents that will be forwarded to the CRO/SPONSOR.

Wherever possible, all data obtained in the course of the Study must be recorded in the original patient files. Data to be recorded directly on the e-CRFs and considered as source data will be

identified as such. All data in the e-CRFs must correspond exactly with data recorded in the source documents.

iv. If e-CRFs are not complete the Principal Investigator shall be obliged to complete them on request of CRO/SPONSOR.

j) Drug Safety: The recording of Adverse Events (AEs) is an important aspect of study documentation. It is the Principal Investigator's responsibility to document all AEs according to the detailed guidelines of the Protocol. The Principal Investigator agrees to answer any questions of CRO/SPONSOR Medical Monitors concerning any AEs. According to the Protocol, the Principal Investigator will assess at each visit whether any Adverse Event (AE) including abnormal laboratory values has occurred. The details of all AEs, whether reported by the patient or observed by the Principal Investigator/Study personnel during the entire study, will be recorded onto the appropriate source document. Each adverse event must be recorded in the AE section of the electronic case report form (e-CRF), regardless of the causal relationship. The Principal Investigator must immediately report all Serious Adverse Events (as defined in the Protocol), which occur during the course of the Study and up to the date of the patient´s last visit, to the addressee given below. The SAE Report Form will be used for documentation and reporting. Initial and follow up SAE reports are to be sent to the Medical Affairs Department of ProRelix Services LLP within 24 hours of the event, for onward transmission to SPONSOR.

Name: Dr. Sornaraja Thasma
Director,

ProRelix Research
Telephone Number: 020-25478064
E-mail: sthasma@prorelixresearch.com

If the event is unexpected and fatal or life threatening and is considered by the Principal Investigator possibly related to the study medication, ProRelix Services LLP shall be informed immediately by telephone and followed immediately by email. CRO/Sponsor will be responsible to notify the health authorities in India on time.

k) Source Data: The Principal Investigator shall be responsible for providing the Source Data according to the following regulations. Source data are the original patient records of all variables collected for the trial as well as the patient's medical history. Specifically they comprise:

i. Signed Informed Consent Form
ii. Patient hospital file and individual clinical notes
iii. Laboratory Reports
iv. Pharmacy Records
v. Study specific source documents (e.g. Lab report, etc)
vi. Appropriate sections of the e-CRF, where data are recorded directly onto specific forms
vii. Other reports and records of any procedure performed in accordance with the Protocol

The Principal Investigator shall safely maintain the original study documentation together with all source data for the maximum period of time permitted by the hospital, research institute or practice in question, but not less than 02 years after the clinical part of the trial has been completed. If archiving can no longer be maintained at site, the Principal Investigator will notify CRO/SPONSOR.

l) Investigator Study File and Archiving: The Principal INVESTIGATOR shall prepare and maintain complete and accurate study documentation in compliance with ICH-GCP standards and local regulations. Therefore, an investigator study file shall be prepared which contains all relevant documents necessary for the conduct of the study:

i. Signed Protocol and Amendments
ii. Investigational Brochure and Updates
iii. EC approval(s)/opinion correspondence/reporting
iv. CVs and signature sheet for key study personnel (e.g. Investigators, Study Nurses)
v. Signed study agreements including financial agreement.
vi. Trial Initiation Report
vii. Approved and signed Informed Consent Forms
viii. Clinical trial Insurance Certificate
ix. E-CRFs(Investigator' s copy)
x. Data Clarification Forms(copies)
xi. SAE documentation and related correspondence/reporting
xii. Shipping/accountability/destruction records for investigational product
xiii. Certificate of Analysis
xiv. Instructions for handling of investigational product
xv. Laboratory accreditation/certification and up-to-date reference ranges of normal values
xvi. Screening, enrollment and monitoring logs and subject identification code list
xvii. Study related correspondence with CRO/SPONSOR

m) Documentation and Material (Supplies): All supplies provided to the Principal Investigator for the purpose of carrying out the Study are supplied only for the purpose of the Study and must not be used for any other purpose whatsoever. The Principal Investigator, or a person(s) delegated by him, are responsible for the security and accountability of all supplies.

n) The inventory must be available for monitoring, auditing and inspection. When the study is completed, or if it is prematurely terminated, any supplies of unused material for the Study, supplied by the CRO/SPONSOR (except documentation required to be retained by the Principal Investigator), must be returned to the CRO/SPONSOR or destroyed at site, alternatively. In the latter case, the identification and quantity of each unit of study medication, the method of destruction and the person in charge must be documented.

o) Monitoring, Quality Assurance and Inspection by Authorities: The Study will be monitored by the CRO. Its representatives (alone or together with representatives from SPONSOR) will be allowed access to all information resulting from this Study and SPONSOR will have an unrestricted right to use such information. CRO (alone or together with representatives from SPONSOR) will perform regular on-site monitoring visits / remote monitoring throughout the Study. The tasks of the monitor comprise the following:

i. to ensure Protocol adherence
ii. to verify the data in the e-CRFs against source documents(SDV)
iii. to check progress of the study and to motivate, if necessary
iv. to review the e-CRFs for complete and accurate capture of data, including laboratory test reports and other patient records
v. to check all data for possible SAEs and AEs
vi. to review signed informed consent forms for signatures and date of consent
vii. to ensure accurate record of drug accountability
viii. to ensure adequate storage of study supplies
ix. to collect completed e-CRFs
x. to discuss and help resolve any problem/s

p) Source Data Verification (SDV) shall be performed on 100% of key data such as informed consent, demographics, inclusion/exclusion criteria, parameters for the evaluation of the main endpoints, safety evaluation and drug accountability.

q) The visits shall involve the Principal Investigator or his appointed representative(s) and any other staff, as required. The Principal Investigator shall ensure that sufficient time is allowed for monitoring visits. Follow-up correspondence between the Site and the CRO relating to apparent inconsistencies or clarification of e-CRF entries will be kept on file at both CRO and the Site.

r) Study Protocol, Patient Information Leaflet/Consent Forms, e-CRF and Trial Report as well as each step of data recording, monitoring and processing shall be subject to the independent Quality Assurance at CRO.

s) This Study can be audited on behalf of SPONSOR to assure GCP compliance as well as validity of the study data.

t) For monitoring visits and in case of audits and inspections by authorities, the Principal Investigator must provide direct access to the complete study records including e-CRFs, original source data, study documentation, and, if necessary, any additional background data. Furthermore, access to Study related facilities must been assured.

u) Confidentiality of Patient Records: The Principal Investigator must assure that Study patients' anonymity will be maintained, and that their identities will be protected from unauthorized parties. Documents stating patients' names must be kept in strict confidence by the Principal Investigator. On e-CRFs or other documents removed from the Study Site, patients must not be identified by their names, but by initials and patient identification number. The Principal Investigator is obliged to maintain a subject identification code list showing the patients' full name and date of birth together with the corresponding patient identification number to allow revealing identity of any subject.

v) The Principal Investigator agrees that representatives of CRO/SPONSOR, of the responsible EC/IRB and of national or international regulatory authorities may inspect the patient records at the site for source data verification. SPONSOR and CRO guarantee for their representatives that patient data will be treated confidentially. Monitors and Auditors are further bound to secrecy.

4. AMENDMENTS: The CRO, on behalf of the SPONSOR, may from time to time, make changes to the Protocol. Changes in the Protocol must take the form of written amendments and shall be approved by all signatories of the final version of the Protocol. Any amendments to the Protocol which affect the patient (e.g. changes in procedures/assessments or matters relating to patient safety) require approval of the relevant ethics committee as well as further informed consent from each concerned patient prior to implementation. The Principal Investigator shall obtain such approval. Changes of purely administrative nature shall be notified to the committee by the Principal Investigator, but do not require formal approval.

5. INSPECTIONS:

a) By Representatives of CRO/SPONSOR: The Principal Investigator agrees that CRO/SPONSOR's representatives and clinical monitors for the Study will have free access to the Principal Investigator's/Study Site's facilities and all documents pertaining to the Study during normal business hours, after provision of prior written notice, as is necessary to ensure that the Study is conducted in accordance with this Agreement. In the event any such representative or monitor observes non-compliance with this Agreement, incomplete, illegible or inaccurate recording of Study data, or other matters of concern relating to the Study, the Principal Investigator shall, in cooperation with such representative or monitor, promptly remedy such non-compliance, Study data recording problems or matters of concern and shall promptly notify such representative or monitor of such remedial actions taken.

b) By Governmental Representatives: The Principal Investigator/Study site agrees that representatives of the government will have access to its facilities and such documents pertaining to the study as may be legally requested by such representatives. The Principal Investigator/Study site shall not disclose individually- identifiable personal information, individually-identifiable health care information or other Confidential Information to such governmental representatives except as required by law, and if the Principal Investigator/Study site discloses such individually-identifiable information or other Confidential Information to such governmental representatives, the Principal Investigator/Study site shall seek an appropriate, written agreement of confidentiality from such governmental representatives prior to making such disclosure. The Principal Investigator/Study site shall promptly provide copies to the CRO/SPONSOR of any notices, correspondence and other documentation received or prepared by or on behalf of the Principal Investigator/Study site in connection with any governmental inspection, action; inquiry or correspondence relating to or that may affect the Principal Investigator's/Study Site's activities under the Study. The Principal Investigator/Study site shall take all actions necessary to remedy any non-compliance cited by governmental authorities and shall promptly notify CRO/SPONSOR of such remedial actions taken.

6. WARRANTIES AND DISCLAIMER OF WARRANTIES: Principal Investigator/Study site warrants that all services provided under this Agreement will be provided in a professional and workmanlike manner, in compliance with the Standards and the terms of this Agreement.

7. AGREEMENT TERM AND TERMINATION:

a) This Agreement is effective as of beginning of the study, and shall continue until 2 years after completion of study, unless terminated sooner in accordance with this Article 7 or unless extended for a defined period by a signed written amendment in accordance withArticle14.

b) The Study and this Agreement may be terminated by written notice from the SPONSOR/CRO to the Principal Investigator/Study site for any of the following reasons:

i. Notification to CRO/SPONSOR from applicable regulatory authorities to terminate this Study.

ii. Determination by CRO/SPONSOR that the Principal Investigator/Study site is not performing the Study as required in the Agreement and/or is not meeting the agreed upon patient enrollment requirements set forth in Section7(c) herein.

iii. Failure of the Principal Investigator and/or the Principal Investigator/Study site to provide access to the SPONSOR monitors or SPONSOR representatives to the Principal Investigator's/Study Site's facilities and all original medical records and Study-related documents necessary to verify entries on Study Case Report Forms and the Principal Investigator's/Study Site's compliance with this Agreement.

iv. Failure of the Principal Investigator or associated staff, upon reasonable notice and by prior mutually convenient time appointment for any other person engaged in the Study (excluding

patients) to be available by CRO/SPONSOR, to meet with the CRO/SPONSOR monitors or CRO/SPONSOR representatives during the course of the Study as necessary to discuss information relevant to the Study.

v. Unauthorized replacement of Principal Investigator, in accordance with Section7(b)herein.

vi. Determination by SPONSOR that business or scientific considerations require termination.

vii. Case Report Forms provided to the Principal Investigator by the CRO/SPONSOR for use in the Study are not completely, accurately and/or legibly completed and/or forwarded to the CRO/SPONSOR's designated representative, as appropriate, within one (1) week of each patient's visit date.

c) The Principal Investigator/Study Site may terminate this Agreement by written notice from the Principal Investigator/Study Site to the CRO/SPONSOR for any of following reasons:

i. SPONSOR does not comply with the Clinical Trial Protocol provisions related to supply of Investigational Product for the Study, or the CRO/SPONSOR does not supply other agreed-upon study related material.

ii. The Principal Investigator reasonably suspects an adverse reaction/adverse event related to the Study procedure and of serious nature, after informing the Independent Ethics Committees and the CRO/SPONSOR.

d) In case of any termination or expiration of this Agreement:

i. Responsibility for treatment of enrolled patients will be as specified in the Standards;

ii. The Principal Investigator/Study Site shall cooperate with the SPONSOR for an orderly wind-down of activities, with due regard for patient safety and welfare;

iii. The Principal Investigator/Study Site shall return or destroy all Confidential Information to CRO/SPONSOR, at the CRO/SPONSOR's selection, in accordance with Section7(d)(iii)herein;

iv. The Principal Investigator/Study Sites hall promptly provide all Agreement deliverables due to the CRO/SPONSOR and, if requested by the CRO/SPONSOR, provide copies of all Work Product (including without limitation all Trial Data) to CRO/SPONSOR, in accordance with Section 7(d) (ii)herein;

v. The Principal Investigator/Study Sites hall return and/or dispose of fall remaining Investigational Product and other Materials received or obtained hereunder, in accordance with the Protocol, Standards and the directions of CRO/SPONSOR, in accordance with Section7(d)herein;

vi. The Principal Investigator/Study Sites hall, within thirty (30) days after such termination or expiration, provide a final invoice to the CRO;and

vii. The Principal Investigator/Study Sites shall, not withstanding such termination or expiration, remain responsible for compliance with all Standards.

e) The provisions of Articles 5, 6, 7, 8, 9, 10, 12 and 13 herein shall survive any termination or expiration of this Agreement, as shall such other provisions as, by their context, are intended to survive such termination or expiration.

8. RECORDS: The Principal Investigator/Study Site shall maintain in the English language (a) all Work Product; and (b) complete, accurate and legible scientific and clinical documents, books and records pertaining to all activities performed and all Materials provided or obtained under this Agreement. The filled out Case Report Forms and all other Study materials will be archived at the Principal Investigator's/Study Site's archival dept. for the period of 7.5 years. The photocopies of Case Report Forms and all other Study materials will be retained by the Principal Investigator/Study Site and originals given to the CRO for the purposes of data analysis.

9. PUBLICATION OF RESULTS:

a) Both the Principal Investigator/Study Site and CRO shall treat matters of authorship in a proper, collaborative spirit, giving credit where it is due and proceeding in a manner that fosters cooperation and communication.

b) It is hereby expressly made clear that all Intellectual Property Rights in the final test report as well as in the material generated during the process of Clinical trial will reside with the SPONSOR. CRO, Investigator and Principal Investigator/Study Site expressly assign, revoke their rights in respect of the manuscript of the final report and all the material generated in respect thereof during the process of Clinical trial to the SPONSOR.

c) Principal Investigator/Study Site will provide a final report in respect of the trial on its letter head to SPONSOR. Principal Investigator/Study Site will not have any objection in respect of the use of the results of the study alone, after the explicit one time approval from Principal Investigator/Study Site.

e) It is the general policy of the SPONSOR to encourage publication or presentation of results of clinical investigations. After publication of the collaborative manuscript described in Section 9(b) above, the Principal Investigator/Study Site may publish and present information arising out of the Study, subject to the approval of sponsor and restrictions set forth in this Article 9 and elsewhere in this Agreement. However, according to good scientific practice, no interim data shall be published by the Principal Investigator/Study Site unless agreed by SPONSOR. It is further agreed that the manuscript shall be based on the final report of the Study, and at least ninety (90) days before the intended publication or presentation of the manuscript, the manuscript shall be sent to the SPONSOR for perusal and comments. SPONSOR shall undertake to forward the manuscript to the Principal Investigator/Study Site, along with comments, within sixty (60) days of receipt by SPONSOR. The Principal Investigator/Study Site shall give serious consideration to such comments, and if the SPONSOR requests, the Principal Investigator/Study Site shall: (i) delete any Confidential Information; (ii) delete or correct any deductive information that is in SPONSOR's reasonable view, inaccurate, misleading or inappropriate. In addition, SPONSOR will not have any objection to the reporting of the primary data. In no event shall the Principal Investigator/Study Site publish or present the clinical trial Protocol or SPONSOR's Investigator's Brochure concerning the Investigational Product. If the SPONSOR requests, the Principal Investigator/Study Site shall delay such publication or presentation for a further sixty (60) day period to enable the SPONSOR (and/or its other collaborators) to protect its (or their)

rights in such proposed publication or presentation. Promptly after publication or presentation the Principal Investigator/Study Site shall provide the SPONSOR with at least six (6) copies of all such final public actions presentations.

10. FINANCE:

a) The expenses of the Study, as set forth in the total projected budget, shall be paid by the CRO and are estimated not to exceed the amount mentioned in the total projected budget, in case it exceeds it will be mutually agreed upon on reasonable grounds and documented appropriately. The CRO's payment to INSTITUTION is contingent upon the CRO receiving payment from the SPONSOR.

Funds shall be paid by the CRO to the Principal Investigator/Study Site for the satisfactory and timely performance under this Agreement, as per the payment details, terms and conditions laid out in ***Annexure A.***

b) An insurance policy, as relevant, for the participating patients covering any injury or illness suffered as a direct result of their participation in this Clinical Study shall be taken out by the SPONSOR/representative of sponsor. The causal relationship of the event should be determined by the investigator and medical monitor, mutually agreed with the sponsor. All participating patients will be informed by the Principal Investigator about the existence of the insurance policy and the extent of the coverage.

11. PUBLICITY, PRODUCT PROMOTING ACTIVITY AND COMMUNICATION GUIDELINES:

a) The SPONSOR shall not identify or use the names, trademarks, trade names or symbols of the institution, Principal Investigator or his research team under the study without the prior written permission of the Principal Investigator and dean of the institution for claims, publicity or any product promoting activity. because the SPONSOR is a publicly funded organization that must maintain a certain level of transparency about its collaborations, SPONSOR may disclose the identity of the Principal Investigator/Study Site, publicly available information about the Principal Investigator/Study Site and the broad purpose of the collaboration under this Agreement to third parties such as a Court of Law, regulatory agencies, governmental or legal agencies, other collaborators, other investigators involved in the project and the organization (profit or non-profit) funding the development of the Investigational Product. Also such details can be shared in scientific forums and with other medical professionals, if questioned.

b) The Principal Investigator/Study Site shall not identify or use the names, trademarks, trade names or symbols of the SPONSOR, the SPONSOR's employees or affiliates, SPONSOR, SPONSOR's employees, donors or affiliates or any other author of the primary collaborative publication described in Section 11(b) herein for publicity or product promoting activity.

c) The Principal Investigator/Study Site shall not issue any press release concerning the Study or this Agreement without the prior, express written approval of SPONSOR.

12. LIMITATION OF LIABILITY: The parties expressly agree that there shall be no limitation on either party's liability for any claims, damages, losses or liabilities arising out of or related to this Agreement or the services performed hereunder. IN NO EVENT SHALL EITHER PARTY BE LIABLE HERE UNDER FOR ANY INDIRECT, INCIDENTAL, CONSEQUENTIAL, PUNITIVE OR SPECIAL DAMAGES (INCLUDING BUT NOT LIMITED TO LOST PROFITS AND LOSS OFUSEOF FACILITIES) SUSTAINED BY THE OTHER PARTY OR ANY OTHER INDIVIDUAL,THIRDPARTY OR OTHER ENTITY FOR ANY MATTER ARISING OUT OF OR PERTAINING TO THE PATIENT MATTER OF THIS AGREEMENT. THE PARTIES EXPRESSLY ACKNOWLEDGE THAT THE FOREGOING LIMITATIONS HAVE BEEN NEGOTIATED BY THE PARTIES AND REFLECT A FAIR ALLOCATION OF RISK. Any disputes that arise during the study between SPONSOR/CRO /Principal Investigator will be under the jurisdiction of Pune courts.

13. APPLICABLE LAW AND ARBITRATION: This Agreement is entered into and will be deemed for all purposes to have been made in Pune, India and shall be governed and construed in accordance with the laws of India applicable to contracts and agreements. Not withstanding the foregoing, SPONSOR may seek injunctive or equitable relief, in addition to damages, for a breach of any of the confidentiality provisions contained herein in any court of competent jurisdiction. In the event of any dispute arising between parties hereto as to rights and obligations under this agreement or to any claim, monetary or otherwise of one party against the other or as to the interpretation and terms of this Agreement, the parties will attempt, for at least sixty (60) days to amicably resolve such dispute, failing which, the following shall apply:

a. If the parties can agree upon one, the dispute shall be referred to a single arbitrator for a decision. The single arbitrator shall commence the arbitration within seven (7) days of appointment as arbitrator (the "Commencement Date").

b. If the parties cannot agree upon a single arbitrator, then one of the parties may appoint an arbitrator of its choosing and notify the remaining party, in writing, and within fourteen (14) days of receipt of such notice of appointment, the other party shall appoint an arbitrator of its own choosing and notify the other party or parties of such appointment. The arbitrators so appointed shall then, within ten (10) days of the appointment of the last of them, appoint a third person to be known as the umpire. The Board of Arbitration, comprised of the arbitrators appointed by the parties and the umpire, shall commence the arbitration within seven (7) days of the umpire's appointment (the "Commencement Date"), at a location to be determined by the Board of Arbitration.

c. If any party fails to appoint an arbitrator within the prescribed time limit, then the one (1) arbitrator already so appointed shall, at the request of the party appointing him, proceed to hear and determine the matter as if he were a single arbitrator appointed by all the parties for that purpose. The "Commencement Date" shall be the date on which the arbitration commences.

d. Decisions of the majority of the Board of Arbitration, or if only one (1) arbitrator is appointed, then a decision of the single arbitrator, shall be final and binding upon all of the parties and there shall be no appeal from its decision.

e. The Board of Arbitration shall determine the procedure to be followed for the arbitration, but not withstanding the procedure to be followed, the final decision shall be made within 90 days following the Commencement Date.

f. The parties shall share equally the costs of the Board of Arbitration unless the Board determines otherwise.

14. AMENDMENTS: This Agreement may only be amended by and to such degree as specified by the mutual written consent of the parties hereto.

If to CRO:

Mr. Sohal Pendse
Director-Business Operations
ProRelix Services LLP
(ProRelix Research),
102 A/B, Park Plaza, Main Karve Nagar
ChowkKarve Nagar, Pune, 411052,
Maharashtra, India

IN WITNESS WHEREOF, the parties hereto have executed this Agreement in triplicate by proper persons thereunto duly authorized.

For Principal Investigator,

Dr. Sudhir Mourya
Head of Department

31/10/2023

Date:

For Institute,

Dr. G. S. Patel
Dean

31/10/23

Date: 31/10/23

For CRO,

23/Oct/2023

Mr. Sohal Pendse
Designation: Director- Business Operations

Date: 23/Oct/2023

Witness:

1. Name: Sh. Sanjeev Narang
2. Address: A-2, 407, Anandvan, Sc. 140, Indore 452016
3. Sign: 31.10.23

1. Name: Ms. Kausin Patni
2. Address: ProRelix Services LLP (ProRelix Research), 102 A/B, Park Plaza, Main Karve Nagar Chowk Karve Nagar, Pune, 411052, Maharashtra, India
3. Sign: 23/Oct/2023

ANNEXURE A

Site Budget

PI Budget

Sr. No	Details	Per Patient	No. of Patients	Total cost
1	PI & Co-I Charges	6000	20	1,20,000
2	Travel Reimbursement	300 x 5 visits = 1500	20	30,000
3	CRC Charges	2300	20	46,000
4	Institutional Overhead (20 % of PI charges)	1200	20	24,000
			Grand Total for 20 subjects	**2,20,000**

- **PT- INR test will be performed by site lab. The cost per test will be 400 rs which will be provided seprately on monthly basis for the number of test performed in that month.**
- **Blood withdrawal for all the visits would be included in the above budget.**
- **Index Medical College and Hospital will archive study documents for a period of 7.5 years at a cost of 1,00,000 INR which will be paid at the time of study close out.**
- **Any amount apart from agreed budget, to be discussed and approved by CRO.**
- **Full and final settlement of payment will be based on number of subjects completed the study and visits (all data points should be completed to consider the clinical trial to be completed for subject)**
- **There will not be any screening fail charges in addition to the budget mentioned above.**
- **Laboratory assessments will be conducted at the central laboratory selected by the Sponsor.**

Payment Schedule and Terms:

5% Advance after completion of SIV

20%, completion of 10 subject recruitments#

25 %, 10 subject completed visit 3 #

20%, 10 subject completed visit 4#

20% 20 subjects completed visit 5#

10 % upon CSR signature.

Note:-

- Here the milestone is achieved when the corresponding e-CRFs for those subjects are completed.

- The invoice will be raised by the site after the achievement of the specific milestone. After the CRA QC the invoice will be shared with the accounts team for clearance.

Payee Details:

Name of Payee	**Scientific Committee Index Medical College**
Account No	**885610110001780**
Name of Bank	**Bank of India**
Branch Address	**Index Medical College branch**
Contact details of payee	
PAN no	**AANFM0784C**
IFSC code	**BKID0008856**