भारतीय गैर न्यायिक

एक सौ रुपये **Rs. 100**

रु. 100 ONE HUNDRED RUPEES

सत्यमेव जयते

भारत INDIA

INDIA NON JUDICIAL

ఆంధ్రప్రదేశ్ आन्ध्र प्रदेश **ANDHRA PRADESH**

DB 422218

N. PAPAYAMM…
L.V. RAJAMAHENDRAVAR…
L.No. 04-28-010/20…

S.No. 6115 గెలాక్సీ C.R సర్వీసెస్ విశాఖపట్నం.
Date 1/7/2021 Rs.100/-
ప్రో॥ కె. శివాజీ s/o జగన్నాధయుడు.

Clinical Trail Agreement

This Agreement is executed on this 02th day of JUL2021between

GSL EDUCATIONAL SOCIETY (SITE),

6-265.Lakshmi puram, NH-16, Rajanagaram, Rajhamundry, A.P.India, Pin: 533296

AND

GALAXY CR SERVICES (SMO)

Sri Datta Mansion, Flat No: 102, Vivekananda Nagar, Yendada, Visakhapatnam-530045

RECITALS

1. Whereas, Galaxy CR Services is a Site management Organization (SMO), engaged in undertaking the clinical trial (study) on behalf of the sponsor and CRO.
2. Whereas, the site is desirous to participating in the clinical research activities on the terms and conditions as contained in this agreement, and has agreed to do so at GSL Educational Society (Site)
3. Whereas the hospital (site) has agreed to provide its facilities to enable the investigator to conduct the study and SMO has agreed to manage all the site related activities as per the terms and conditions contained in this agreement.

PRINCIPAL
GSL MEDICAL COLLEGE
RAJAHMUNDRY - 533 296

Managing Director,
Galaxy CR Services

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ARTICLE-1: DEFINATIONS & INTERPRETATIONS

AV Consent	Audio/Video recording Informed consent
AE	Adverse Event
CRO	Clinical Research Organization
CRC/SC	Clinical research coordinator/Study Coordinator
CDA	Confidentiality disclosure agreement
CRF	Case report form
DCGI	Drug Controller General of India
DCF	Data Clarification form
GCP	Good clinical practice
ICF	Informed consent form
IEC	Institutional ethics committee
IVRS/IWRS	Interactive Voice/Web response system used for randomizing the subject to study arm
IP/IMP	Investigational product/Investigational medicinal product
ICH	The international conference on harmonization of technical requirement for registration of pharmaceuticals for human use.
New CT Guidelines	Requirement and Guidelines on clinical trials for import and manufacture of new drug
PSV	Pre study visit
PI	Principle investigator
SMO	Site Management Organization
SIV	Site initiation visit
SAE	Serious Adverse event

ARTICLE-2: SCOPE OF WORK

Clinical Trial and Research as per ICH-GCP, Indian GCP, New CT Guidelines2019, ICMR guidelines, other applicable regulatory guidelines.

ARTICLE-3: GSL EDUCATIONAL SOCIETY

A. Obligations of the hospital

1. The Hospital agrees to provide its facilities to enable the investigator to conduct the study.
2. The hospital agrees to provide separate space along with the infrastructure including.AC, Internet connection, Table & Chair, Cupboards, Computers with Desktop, printer with scanner (The space including the mentioned infrastructure shall be the sole and exclusive property of Hospital).

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Managing Director

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ARTICLE -4: GALAXYCRSERVICES OBLIGATIONS

B.Obligation of SMO

The SMO agrees to provide the following clinical Research services to the investigator and Hospital:

1. Developing Clinical Research department as per the requirement of regulatory authorities and study requirement including Equipment like Refrigerator, Deep Freezer, Centrifuge, Weighing Machine, B.P. Apparatus, Stature meter. Thermo hygro meter, thermometers &other study related equipment. (The mentioned infrastructure shall be the sole and exclusive property of Galaxy CR Services).
2. SMO agrees to provided calibration certificates of the machine/equipments used in the study,
3. Providing qualified clinical research professionals for the successful outcome of study.
4. A dedicated Business Development manager to get the projects business for the site.
5. Budgeting

ARTICLE-5: TERMS AND TERMINATION

TERMS OF AGREEMENT

1. The term of this agreement shall be for a period of five years (till close-out of ongoing study) commencing on the effective date. Later the tenure of this agreement can be extended mutually by both parties.
2. Site (hospital) and SMO are independent parties. Both parties agree that their relationship is that of an independent contractor and not employer and employee.

ARTICLE-6: FINANCIAL CONSIDERATIONS

FINANCIAL TERMS

1. The total study grants from the sponsors will be received in the name of GSL Educational Society.
2. The Professional cost study grant payment (65%) will be received from the sponsor in the name of GSL Educational Society, (35%) to Galaxy CR Services.
3. The SMO will make payment to the study staff recruited by the SMO.SMO will recruit CRC, Phlebotomist &Study Nurse.
4. Galaxy CR Services will receive procedural cost grant from the sponsor
5. Galaxy CR Services will pay Hospitalization charges, also other diagnostics and laboratory charges in case of their use as per the rate card to GSL Educational Society
6. Ethics committee review payment will go ethics committee of the hospital and can be used for the execution of ethics committee work as per its SOP.
7. The study initiation/Startup charges received from sponsor is excluded from the above mentioned study grant and shall be used by Galaxy CR Services for the management and up gradation of the study related activities/site facilities at GSL Educational Society.

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Galaxy CR Services

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Study Management Responsibilities Matrix			
S. No.	Activities / Task	PI / Hospital	GALAXY CR SERVICES Experts
A	**Site & PI Selection**		
1	CDA and Feasibility process	X	X
B	**Study Start Up**		
1	Compilation of start-up documents and handling logistics issues at site		X
2	Identification and placement of competent CRCs as per the study requirements		X
3	Training of GALAXYCRSERVICES CRCs /Principal investigators incl. GCP, study specific development /changes and any other training		X
4	Track IEC meetings, oversee and timely ethics committee communication and submission	X	X
5	Attendance in Investigator Meeting during the initiation phase of the study	X	X
6	Ensure dedicated GALAXYCRSERVICES CRC is introduced & recruit at site before Site Initiation		X
7	Create a back- up system of CRC to manage, attrition & extra work load at site		X
8	Define recruitment expectations, strategies and activities (referral plans if any)	X	
9	Adequacy of infrastructure, calibrations of instruments & facilities at the site	X	X
C	**Recruitment / During the Study**		
1	To keep the eligibility records of identified subjects ready and assist Investigator to identify subjects through pre-screening		X
2	Review potential pre-screened subject's records, Screen and Randomize eligible study subject's	X	
3	Explain Protocol, Protocol specific procedures & study requirements to subject, resolve subject's medical queries and administration of Audio-video Consenting	X	
4	Take medical decisions to support medical care or advise subject on clinical care	X	
5	Resolve Subject's non-medical queries		X
6	Support & assist in AV ICF process & documentation of ICF administration		X
7	IVRS ,IWRS activities		X
8	Facilitate and process central/ local lab samples as specified in protocol, arrange shipment of lab samples to local/ central laboratories within timelines		X
9	Communication with all Vendors/Sponsors/ CRO for logistics issues		X
10	Discuss /inform/ escalate general and medical issues to the sponsor/ CRO	X	X

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11	Plan/ schedule Subjects visits, coordinate and complete Subjects visits per Protocol requirements under Investigator guidance; Patient retention and ensure to escalate retention issues, if any.	X	X
12	Acknowledge the receipt of IP, lab supplies and other study materials to Sponsor	*	X
13	Maintain IP and lab supplies storage, accountability and reconciliation at site		X
14	Decide on dosage of Investigational Product (IP) administration to Subjects	X	
15	Dispense IP/ placebo/ study related documents (like diaries etc.) per protocol under investigator's instruction (not administration)	*	X
16	Updating and maintaining Investigator site file to appropriate standard and as per study requirements	*	X
17	Record & maintain: Pre-screening, Identification, Screening & Enrolment log, IP and or comparator(s) accountability & temperature log and any other study specific log	*	X
18	Completion and corrections of CRFs under investigator guidance and ensure that all the source are completed on time for timely completion of CRF	*	X
19	Resolve data queries and data clarification forms requiring medical and non- medical opinion under investigator guidance	*	X
20	Participate in Subject recruitment discussion via teleconferences and face to face meetings during study duration with Sponsor/ CRO	X	X
21	Review and Final sign off of CRF during database lock	X	
22	Assist PI with ongoing EC submissions (Protocol amendments, revised ICFs, annual study status reports), follow-up for approvals as applicable and notification of safety updates and any other study updates during the course of the study		X
23	Recording and maintaining source data for each subject and follow-up with delegated study team members to ensure that the required study documentation is completed in a timely manner	*	X
24	Prepare and make documents available for monitoring visit and support site for audits and inspections	*	X
25	Resolve the action items from monitoring visit follow up letters under investigator guidance	*	X
26	Participate in Audit/ Inspection	X	X
27	Track any manpower/ performance issues and mitigate them in timely manner	*	X
28	Raising of Invoices and tracking of payments received from the Sponsor/ CRO		X
29	Supports PI to develop and update site standard operating procedures for the tasks performed for trial		X
30	Document AEs according to required standards under PI's supervision	*	X
31	Ensure adequate medical care is provided to trial subjects for any AE or SAE and also reporting of all serious and unexpected AEs to Sponsor, EC, DCGI & Head of Institute with defined timelines.	X	X

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D	Follow- up phase/ After the study		
1	Resolution of data queries during the Data base lock	*	X
2	Follow-up for safety and efficacy; maintain telephonic contact with trial subjects	*	X
3	Ensure Investigator site file updating	*	X
4	Support and co-ordination during close-out visit	*	X
5	Attend de-brief meeting of study completion	X	X
6	Archival of all clinical trial related documents for 15 years.	X	

Notes:

- The Principal Investigator is overall responsible for the conduct of the study at the site but PI could delegate these activities to SMO CRC

1. The GALAXYCRSERVICES CRC reports functionally to the Principal Investigator at site, and also line reports to the GALAXYCRSERVICES- Project Manager who periodically visits the site.
2. GALAXYCRSERVICES role is to support the performance of the GALAXYCRSERVICES CRC including - line management activities, tracking of performance metrics (related to enrollment, e-CRF data entry timelines, query resolution timelines, action item resolutions post monitoring & overall data- quality at site etc.)
3. The GALAXYCRSERVICES site coordinator will follow the public holidays & attendance policies of the hospital/ site

IN WITNESS WHERE OF, this Agreement has been executed on 06NOV2020by duly authorized representatives of the parties.

1. Agreed and executed on behalf of the:
   GSL Educational Society (site)
   Dr.V.Gurunath, (Principal)

   PRINCIPAL
   GSL MEDICAL COLLEGE
   RAJAHMUNDRY - 533 296

   G.S.L. MEDICAL COLLEGE ★ RAJAHMUNDRY ★

2. Agreed and executed for and on behalf of:
   Galaxy CR Services (SMO)
   S.Gireesh (Head-Clinical Operations)

   Managing Director,

   Galaxy CR Services

Witness:

1 :.....

2. :.....

Managing Director

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INSTITUTIONAL ETHICS COMMITTEE
GSLMCGH, GSL MEDICAL COLLEGE HOSPITAL

6-265, Lakshmipuram, NH-16, Rajanagaram, Rajahmundry, East Godavari,
Andhra Pradesh – 533296
Telephone: 08836699999, **Fax** – 08832484999, **E-Mail:** iecgslmc@gmail.com

Date: 19-Aug-2021

From,
The Chairman/Member Secretary
Institutional Ethics Committee,
GSL Medical college and Hospital,
Rajahmundry, Andhra pradesh-533296.

To,
Dr.Yadlapalli.C.Deepak
Consultant in Medical oncology,
GSL Trust Cancer hospital,
GSL Medical College and hospital,
Lakshmipuram, Rajanagaram,
Andhra Pradesh-533296.

Protocol: CR 194-18

Protocol title:

A Multicentric, Open-label, Randomized, Two Period, Two Treatment, Two Sequence, Crossover, Multiple Dose, Ste-ady state Bioequivalence Study of Sunitinib Malate Capsules 50 mg of Eugia Pharma Specialities Limited (A Joint venture of Aurobindo Pharma Limited & Celon Laboratories Limited), India (Test) with Sutent® (Sunitinib Malate) capsules 50 mg of Pfizer Labs, USA (Reference) in adult patients with advanced renal cell carcinoma already receiving stable dose of Sunitinib Malate Capsules 50 mg under fasting conditions.

Dr. Yadlapalli C.Deepak

Institutional Ethics Committee reviewed and discussed your application dated **09-Aug-2021** to conduct the research study "A Multicentric, Open-label, Randomized, Two Period, Two Treatment, Two Sequence, Crossover, Multiple Dose, Steady state Bioequivalence Study of Sunitinib Malate Capsules 50 mg of Eugia Pharma Specialities Limited (A Joint venture of Aurobindo Pharma Limited & Celon Laboratories Limited), India (Test) with Sutent® (Sunitinib Malate) capsules 50 mg of Pfizer Labs, USA (Reference) in adult patients with advanced renal cell carcinoma already receiving stable dose of Sunitinib Malate Capsules 50 mg under fasting conditions.." during the IEC meeting held on **18-Aug-2021 at 03:30 pm** through Zoom meet app.

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INSTITUTIONAL ETHICS COMMITTEE
GSLMCGH, GSL MEDICAL COLLEGE HOSPITAL

6-265, Lakshmipuram, NH-16, Rajanagaram, Rajahmundry, East Godavari,
Andhra Pradesh – 533296
Telephone: 08836699999, Fax – 08832484999, E-Mail: iecgslmc@gmail.com

The following documents were reviewed and approved:

S. No	Document	Version and Date
1	Study Protocol	CR194-18; Version 1.0, Amendment-01 Dated 21.10.2020
2	English Version Informed Consent Form(s)	Version 1.0, Amendment-01 Dated 05.11.20
3	Hindi Version Informed Consent Form(s)	Version 1.0, Amendment-01 Dated 05.11.20, Translated on 21.12.20
4	Hindi to English Back Translation Informed Consent Form(s)	Version 1.0, Amendment-01 Dated 05.11.20, Back translated on 22.12.20
5	Direct Translation Certificate English to Hindi (ICF)	Dated 21.12.20
6	Back Translation Certificate Hindi to English (ICF)	Dated 22.12.20
7	Telugu Version Informed Consent Form(s)	Version 1.0, Amendment-01 Dated 05.11.20, translated on 24.12.20
8	Telugu to English Back Translation Informed Consent Form(s)	Dated 25.12.20
9	Direct Translation Certificate English to Telugu (ICF)	Dated 24.12.20
10	Back Translation Certificate Telugu to English (ICF)	Version 1.0, Amendment-01 Dated 05.11.20, translated on 25.12.20
11	Patient Diary Version English	Version 1.0 dated 24.11.20
12	Patient Diary Version Hindi	Version 1.0 dated 25.12.20
13	Hindi to English Back Translation Patient Diary	Version 1.0 Dated 24.11.20, translated 25.12.20
14	Direct Translation Certificate English to Hindi (Patient Diary)	Dated 25.12.20
15	Back Translation Certificate Hindi to English (Patient Diary)	Dated 25.12.20
16	Patient Diary Version Telugu	Version 1.0 dated 29.12.20
17	Telugu to English Back Translation Patient Diary	Version 1.0 dated 29.12.20
18	Direct Translation Certificate English to Telugu (Patient Diary)	dated 29.12.20
19	Back Translation Certificate Telugu to English (Patient Diary)	dated 29.12.20
20	Final eCRF/eCRF guidelines	NA & Dated 23.03.21/24.03.21
21	BENOC (CR194-18 Version 1.0, Amendment-01 Dated 21.10.2020)	NA & Dated 12.02.2021
22	Import licence (Number of Licence: TL/BE/19/000069)	NA & Dated 11.01.2019
23	Draft CTRI (CTRI/2021/03/031750)	Registered on: 05/03/2021
24	Prescribing information Sutent	NA

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INSTITUTIONAL ETHICS COMMITTEE
GSLMCGH, GSL MEDICAL COLLEGE HOSPITAL

6-265, Lakshmipuram, NH-16, Rajanagaram, Rajahmundry, East Godavari,
Andhra Pradesh – 533296
Telephone: 08836699999, **Fax** – 08832484999, **E-Mail**: iecgslmc@gmail.com

The following members of the Institutional Ethics Committee (IEC-GSL) were present at the meeting held on **18-Aug-2021 at 03:30 pm** through Zoom meet app.

S.No	Name of member	Qualification	Position in IEC	Affiliation to the institution	Gender
1	Dr. V.D.N.Suryanarayan sarma	MA, LLB	Chairperson	No	M
2	Dr. V.S.Gurunath	M.B.B.S.,M.S (Ophthalmology)	Member Secretary	Yes	M
3	Dr. K. Ravi babu	M.B.B.S., M.D (Pharmacology)	Basic Medical Scientist	Yes	M
4	Dr. Y.C. Deepak	M.B.B.S., M.D, D.M (Medical oncology)	Clinician	Yes	M
5	Dr. Chakravarthy D.J.K	M.B.B.S., M.D (General Medicine)	Clinician	Yes	M
6	Dr. K. Nageswara rao	M.Com, C.A.I.I.B	Social Scientist	No	M
7	K.Srinivas rao	LLM (Business law)	Legal Expert	No	M
8	Mrs. P. Varalakshmi	9th class	Layperson	No	F

The study is approved in its present form, Trial to be conducted in its present form. It is mandatory to submit study status report Quarterly and the re approval need to be taken if in case the study is not going to be initiated in 1 year from the date of approved

The Ethics committee to be informed about the progress of the study, any changes in the protocol, patient information Sheet or informed consent.

Following points must be noted:

1. IEC should be informed of the quarterly progress of the study by the PI. Failure to submit the continuing review application/annual status report may result in withdrawal of IEC approval.
2. IEC has approved the conduct of the study at **GSL Medical College and Hospital.**
3. The decision was arrived at through consensus/unanimous or majority opinion amongst the voting members of IEC. Member(s) of the committee who is/are listed as investigator(s) on a research proposal opted out from all deliberations on the proposal and did not participate in decision making. Neither PI nor any of proposed study team members participated during the decision making of the IEC.
4. The IEC functions in accordance with its SOP and is compliant with the new clinical trial rules dated 19th March 2019, ICMR guidelines and ICHGCP.

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INSTITUTIONAL ETHICS COMMITTEE
GSLMCGH, GSL MEDICAL COLLEGE HOSPITAL

6-265, Lakshmipuram, NH-16, Rajanagaram, Rajahmundry, East Godavari,
Andhra Pradesh – 533296

Telephone: 08836699999, **Fax** – 08832484999, **E-Mail:** iecgslmc@gmail.com

5. In the events of any protocol amendments, IEC must be informed and the amendments should be highlighted in clear terms as follows:

   a) The exact alteration/amendment should be specified and indicated where the amendment occurred in the original project. (Page no. Clause no. etc.)

   b) Alteration in the budgetary status should be clearly indicated and the revised budget form should be submitted

   c) If the amendments require a change in the consent form, the copy of revised Consent Form should be submitted to Institutional Ethics Committee for approval.

   d) If the amendment demands a re-look at the toxicity or side effects to patients, the same should be documented.

   e) If there are any amendments in the study design, these must be incorporated in the protocol, and other study documents. These revised documents should be submitted for approval of the SRC and IEC, only then can they be implemented.

   f) Approval for amendment changes must be obtained prior to implementation of changes. Without including all the above points, the amendment is unlikely to be approved by the IEC.

   g) Any deviation/violation/waiver in the protocol must be informed to the IEC.

Thanks & regards

Chairman/Member secretary
Institutional Ethics Committee
GSL medical college and Hospital
Rajahmundry.

CHAIRMAN/MEMBER SECRETARY
INSTITUTIONAL ETHICS COMMITTEE
GSLMCGH
Regd.No.ECR/1534/Inst/AP/
RAJAHMUNDRY, A.P., I.

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Institutional Overhead	Per Patient on PI Grant @ 20%	20,000/-
Printing, Stationery, Communications	Per Month	3000/-
Archival of Study Documents	5 Years	As per Actuals

All amounts stated in this Fee and Payment Schedule is exclusive of any or all applicable tax and the same shall be borne by the Sponsor.

a) Miscellaneous Expenditure (If any) related to the clinical study shall be paid as per the actuals after the approval from the Sponsor.

b) EC fees will be paid by sponsor as per IEC SOP

c) Archival is as per actuals to be covered by Sponsor or provided by Sponsor

d) Cost of clinical supplies (vials, etc) needed for the trial will be borne by Sponsor or provided by sponsor

e) All Shipping costs to be borne by Sponsor

f) Trial insurance will be covered and paid by sponsor

II. Payment

a. Sponsor shall make the payments in Indian Rupees according to Subject recruitment milestone achieved.

III. Account Details

The site hereby instructs CRO to pay the entire Investigator fee under this Agreement to the following bank account:

Issuing Entity	ClinSync
Payer Name	CLINSYNC CLINICAL RESEARCH PRIVATE LIMITED
Account Number	000805018545
PAN /TAX ID No:	36AAECC3366N1ZB
IFSC code	ICIC0000008
Branch Name and Address	ICICI Bank Ltd. Khairtabad Branch, 6-2-1012, TGV Mansions, Opp Institution of Engineers, Khairatabad Rd, Taj Enclave, Khairtabad, Hyderabad, Telangana 500004
Contact	9223393438
Payee-1	**GALAXY CR SERVICES** **Research company payment (SMO)**

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Transaction Successful

05:30 PM on 23 Aug 2021

Transaction ID
T2108231730146457773063

Paid to

GSLMC
XXXXXXXXXXX5296
Axis Bank
₹50,000

Debited from

****014268
UTR:123525176609
₹50,000

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COMPASS
ENTERPRISES PVT.LTD

GSL Campus, NH-16
Lakshmipuram,Rajanagaram
, Rajahmundry,AP 533296,
+91883-2483016

Dt : 14--08-2020

We are happy to inform the Principal of GSL Dental college that the research proposal of your staff has been accepted by our company and we are funding for their research projects . A total sum of RS 44,250/- has been allotted to their projects . The following is the list of the distribution of the grants .

1. **Principal investigator : Dr K.Ramya Rs- 25,000/-**

   Title :Association between concha bullosa and nasal septum with sinusitis a retrospective radiological study

2. **Principal investigator : Dr A.D.N .Deepika Rs- 19,250/-**

   Title : .morphometric evaluation of the orbit in gender identification using CBCT : A Tool in forensic odontology

The principal investigators are requested to complete the research project with in a period of 1year and submit the project report to the company s along with the outcome of the research project up on submission of the report. The principal investigators are also directed to use the infrastructure at the institute it self .

AUTHORISED SIGNATORY

COMAPSS ENTERPRISES PVT.LTD

CUBE
DENTAL EQUIPMENTS

cubedentalequipments@gmail.com
Mob : 87545 75856

Dt : 19--1-2021

Hi Sir/Madam,

We are happy to inform the Principal of GSL Dental college that the research proposal of your staff has been accepted by our company and we are funding for their research projects . A total sum of RS 70,000/- has been allotted to their projects . The following is the list of the distribution of the grants Up on recieval of the grant the principal investigators are directed to make use of the funds with the available infrastructure and complete the project within one and half year and submit the completed research report for the approval of the company. We wish all the investigators will do their best .

1. **Principal investigator : Dr Ashok .K.P Rs- 25,000/-**

   Title : Comparison of open flap debridement withbone graft and open flap debridement with sticky bone in intrabony defects

2. **Principal investigator: Dr M.Anupama . Rs- 25,000/-**

   Title: Comparison of periosteal pedicle graft andsub-epithelial connective tissue graft for the treatment of gingival recession defects: A clinical study

3. **Principal investigator : Dr T.Manikanta kumar Rs- 20,000/-**

   Title : .Comparative efficiency of Hiora 0.2%chlorhexidine and perioaid mouthwashfor plaque control

For CUBE DENTAL EQUIPMENTS

Proprietor

Plot No.3, Ekambaram Street, Udhaya Nagar Extn., (Near PJN Mahal), Porur, Chennai - 600 116.