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Study Budget

Study Title	Evaluation of Safety and Efficacy of Hydroxychloroquine Sulfate as an Adjunct to Diet and Exercise to Improve Glycemic Control in Type 2 Diabetes Patients Uncontrolled on Sulfonylurea + Metformin Combination
Protocol ID:	Ipca/HCQS/PIV-14
Name of Investigtaor	Dr. Ashok Dutt Mathur
Name of Institution	Department of General Medicine, Jaipur National University, Institute of Medical Sciences and Research Center, Jagatpura, Jaipur-302017, Rajasthan

Number of patients (20)	Heads	Proposed Amount (Rs.) (for 20 patients)
1	Investigator's Fees (Rs. 12,500/- per patient cost for 1 screening visit, 6 follow up visit and 7 telephonic follow up)	250,000.00
2	LCG (Rs. 200 - 3 visits)	12,000.00
3	Cost of Opthalmology examination (Rs. 3000 - 3 VISITS)	60,000.00
4	LC fees (if any)	25,000.00
5	Cost of study staff	150,000.00
6	Phelobotomist remuneration	10,000.00
7	Patient Conveyance and other allowance (Rs 200 - 7 visits)	28,000.00
8	Total	535,000.00
9	Institutional Overhead Charges (20%)	107,000.00
10	Total	**642,000.00**

Note:

1. The total budget is for 20 patients completing the treatment period. The budget will be adjusted on pro rata basis (depending upon the number of visits completed by the patients), if the principal investigator could not complete the required number of patients within the stipulated time.
2. ESR, LCG and ophthalmology examination will be performed at the site by investigator. Cost of LCG and Ophthalmology examination is included in the proposed budget. ESR tubes will be provided by central laboratory.
3. All other investigations as per the protocol will be performed by the central laboratory and cost for the same will be paid by sponsor of the trial.
4. Blood smears, if applicable, have to be prepared at the site by investigator's study staff.
5. For laboratory investigations, site has to send the blood and urine samples to central laboratory as per the laboratory requirement. (Sample pick-up will be arranged by central lab.)
6. Ophthalmology examination will include Amsler Grid Test, Visual Field Test, Visual Acuity Test, Expert Slit Lamp Test, and Ophthamoscopy.
7. TDS will be deducted (as applicable) from your total budget for a transaction done on personal account or private institutes.
8. Principal Investigator has to refund the payment(s) [the gross amount of the Cheque including the TDS] made by the "Sponsor" if he/she fails to recruit any patient on the study and/or if the site study members are found to be repetatively non-compliant to the study protocol and/or GCP guidelines.
9. The trial will be conducted on the competitive basis for enrollment of patient at all centers.
10. The study may be terminated at sponsor's discretion, if there is poor rate of randomization/ enrollment of patients at the site.
11. The initial allotment of number of patients to the site will be at the discretion of the sponsor.

Dr. Ashok Dutt Mathur

Investigators Signature, Date & Stamp

5.7.13

(Prof. D K Mathur)
Registrar
Jaipur National University
Jaipur

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PAYMENT SCHEDULE

Sr. No	No. of Installment	Amount as per installment (Rs.)	Schedule
1	1st Installment	25,000.00	EC fees
2	2nd Installment	30,850.00	At the time of initiation
3	3rd Installment	61,700.00	After recruitment of 3 Patients
4	4th Installment	215,950.00	After randomization of 12 Patients
5	5th Installment	215,950.00	After randomization of 20 Patients
6	6th Installment	92,550.00	After resolution of all DCF and signature of Investigator on CSR
	Total	642,000.00	

Dr. Ashok Dutt Mathur

5.67.17

Investigators Signature, Date & Stamp

(Prof. D K Mathur)
Registrar
Jaipur National University
Jaipur

BUDGET STATEMENT

Study Title	Evaluation of Safety and Efficacy of Etodolac Injection in patients with Postoperative Orthopedic Pain
Protocol ID:	Ipca/ETDI/PIV-15
Study Center	Department of Orthopedics, Jaipur National University, Institute for Medical Sciences and Research Centre, Jagatpura, Jaipur-302017, Rajasthan.
Name of Investigtaor	Dr. Ashish Sharma.

Number of patients (30)		**Proposed Amount (Rs.)**
Heads		
A	Investigator's Fees	200,000.00
B	ECG (@ 200 /test) * 2	12,000.00
C	X-ray examination (Rs. 300/ test)	9,000.00
D	Cost of Study Staff	50,000.00
E	**Total**	**271,000.00**
F	Instituional Overhead (20%)	54,200.00
G	**Grand Total**	**325,200.00**

Payment S.No. (A,B,C,D & G) to be made by cheque/DD in favor of - JNU Society for Social Welfare.

Note:

1. The total budget is for (30) patients completing the treatment period. The budget will be adjusted on pro rata basis (depending upon the number of visits completed by the patients), if the principal investigator could not complete the required number of patients within the stipulated time.
2. ESR, X- ray and ECG will be performed at the site by investigator and cost of X -ray & ECG is included in the budget. ESR tubes will be provided by central laboratory.
3. All other investigations as per the protocol will be performed by central laboratory and cost for the same will be paid by sponsor of the trial directly to the central laboratory.
4. Blood smears, if applicable, have to be prepared at the site by investigator's study staff.
5. For lab investigations investigator has to send the blood and urine samples to Metropolis, Mumbai as per the laboratory requirement. (Sample pick-up will be arranged by central lab.)
6. TDS will be deducted (as applicable) from your total budget for a transaction done on personal account or private institutes.
7. Principal Investigator has to refund the payment(s) [the gross amount of the Cheque including the TDS] made by the "Sponsor" if he/she fails to recruit any patient on the study and/or if the site/study members are found to be repetitively non-compliant to the study protocol and/or GCP guidelines.
8. The trial will be conducted on the competitive basis for enrollment of patient at all centers.
9. The study may be terminated at sponsor's discretion, if there is poor rate of randomization/ enrollment of patients at the site.
10. The initial allotment of number of patients to the site will be at the discretion of the sponsor

Dr. Ashish Sharma

Investigators Signature, Date & Stamp

(Prof. D K Mathur)
Registrar
Jaipur National University
Jaipur

PAYMENT SCHEDULE

Sr. No	No. of Installment	Amount as per installment (Rs.)	Schedule
1	1st Installment	16,260.00	Upon starting the recruitment
2	2nd Installment	32,520.00	After randomization of 5 Patients
3	3rd Installment	113,820.00	After randomization of 15 Patients
4	4th Installment	113,820.00	After randomization of 30 Patients
5	5th Installment	48,780.00	After resolution of all DCF and signature of Investigator on CSR
	Total	**325,200.00**	

Dr. Ashish Sharma

Investigators Signature, Date & Stamp

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Annexure-A

BUDGET APPROVAL SHEET

Name of PI	Dr. Anubhav Gupta
Site Name	JNUIMSRC, Jagatpura, Jaipur, Rajasthan
Study Title	A multi-centric, randomized, double blind, parallel group, active controlled, comparative Phase III clinical trial to evaluate the efficacy and safety of FDC of Mirabegron 25mg/50mg (ER) plus Solifenacin succinate 5mg/5mg tablet versus Mirabegron 25mg/50mg (ER) tablet, Solifenacin succinate 5mg tablet in subjects diagnosed with Overactive bladder.
Study Protocol Number	WIN/CT/004/MIR/SOL/2018, Version 1.1 Dated 28Jul2018
Particulars	• Total No of Patients — Sixty six (45) • Total No of Visit — Eight (08) • Total Study Duration — 120 days • Screening Duration — (-3 to-1 days) 3 days • Active Duration — Ninety (90) days • Follow up Period — Thirty (30) days

Remuneration for Principal Investigator (PI) and study Team:

Particulars	Cost Per Patient (INR)	No. of Patients	Amount (INR)	Sub-Total (INR)
Screening visit	700.00X1=700.00	45	31,500.00	3,19,500.00
Treatment Duration	1000.00X5=5,000.00	45	2,25,000.00	
Follow Up	700.00X2=1,400.00	45	63,000.00	
Total Cost	7,100.00	45	3,19,500.00	
Study Archival charge (almirah cost)				10,000.00
Grand Total (INR)				**3,29,500.00**
In words: Three lacs fifty four thousand five hundred rupees only.				
Lab cost (will be paid as per actual invoice)				
Ethics Committee Charges (as per IEC fees)				25000.00

Note:

- Applicable TDS will be deducted.
- Screen failure for maximum of five (05) subjects will be given at a rate of Rs.400.00 per subject.
- Treatment drop out charges (based on number of visits made) will be paid for 20% of total randomized patients.
- Number of study subject is subjected to change.

"For treatment duration the payment will be made on actual treatment days completed by the subject. Similarly, for follow-up visits payment will be made on actual visits completed by the subject."

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Initials INSTITUTION

Initials INVESTIGATOR

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Jaipur National University
Jaipur

Jaipur National University
Institute for Medical Sciences and Research Centre
Jagatpura, Jaipur-302017
Department of General Medical

INVESTIGATOR AGREEMENT

Regarding the Conduct of the Following Clinical Trial

Study Title: A blood test to provide high quality DNA and/or plasma linkable to clinical information as a resource for the research.
(Protocol No: SCR/PNS/2019/001)

Investigator Agreement, dated as of 16 AUG day of 2019, by and among **Spectrum Clinical Research Pvt. Ltd.** with an address at 401, 4th Floor, Kshamalaya, 37, New Marine Lines, Mumbai, 400020, India hereinafter referred to as "SCR" and **Dr. Jaswant Goyal** with an address at Jaipur National University Institute for Medical Sciences and Research Centre, Agra – Jaipur Road, Near New RTO Office, Jagatpura, Jaipur, Rajasthan 302017 hereinafter referred to as "Investigator" and Jaipur National University Institute for Medical Sciences and Research Centre, Jagatpura, Jaipur hereafter referred as "Institute." **Pensieve Health** is hereinafter referred to as the `SPONSOR'.

THE KAPOL CO-OP. BANK LTD. FORT BRANCH (AUTHORISED SIGNATORY)

भारत INDIA 11588 127600 SPECIAL ADHESIVE AUG 16 2019 13:49 MAHARASHTRA

(Prof. D K Mathur)
Registrar
Jaipur National University
Jaipur

19.8.19

Section 1. Conduct of Study

1.1 Administration of Contract. SCR, a Contract Research Organization engaged by the SPONSOR for services relating to this study shall, except as provided herein, administer all aspects of this Agreement and the study on SPONSOR`s behalf until notice indicating otherwise is provided by SPONSOR to the parties hereto.

1.2 Independent Contractor Status. Investigator's relationship to SCR under this agreement is one of independent contractor, and Investigator has no authority to bind or act on behalf of SCR and will deal exclusively with SCR for the purpose of this study.

1.3 Institution Staff Bound. Investigator represents to SPONSOR and SCR that each of his staff members working on the study including each Investigator, co-investigator, sub-investigator, pharmacist, nurse, technologist, and coordinator has read and agreed to this agreement by signing on behalf of self and the entire team in the form set forth in Exhibit B.

1.4 Study Participant Information, Consent. Investigator will consider patients receiving preventive /Clinical care or as specified in the protocol, for enrollment in the study. Before inclusion in the study, Investigator shall inform potential study participants orally and in writing about the clinical study including its risks, benefits, tests and procedures, and shall obtain written IRB-approved informed consent from each participant for participation in the clinical trial. The form for such consent shall be provided by SPONSOR or SCR. The laboratory results generated in the study will not be revealed to Investigator or study participants. Investigator agrees to independently evaluate all study participants according to Protocol.

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Jaipur

1.5 Projected Study Participant Recruitment Period. Investigator shall use his best efforts to enroll patients undergoing biomedical testing at site as described in the Protocol over a specified period of enrollment starting from the Site Initiation by SCR or Sponsor. SCR may upon notice shorten or enlarge the enrollment period. SCR has the option to increase or decrease the number of Patients enrolled by the investigator.

1.6 General Duties of Investigator. Investigator shall ensure that the Investigator shall carry out his duties hereunder in a professional and ethical manner.

1.7 Certain Specific Duties of Investigator. More specifically, Investigator shall:

a) Compliance with Protocol. Conduct the study pursuant to the terms of this agreement and in strict adherence to the study protocol, any amendment thereto and any other written instructions that may be provided from time to time from SCR to Investigator.

b) Compliance with Law. Comply with all applicable laws, regulations and guidelines.

c) Study Participant Information. Maintain a screening log and study participant identification and contact list.

d) Retention of Study Data. Store all documents related to the protocol, which may be subject to change and will be conveyed to Investigator by SCR.

e) Data Documentation. Perform all necessary investigations completely and correctly and continuously document study data of study participants in the study on the case report forms (CRF) provided by SPONSOR as soon as the information becomes available, and document all other relevant data (e.g. informed consent, date of visits, etc.) on the CRF.

f) Return of Materials. Return to SPONSOR the unused Investigational Product, and unused CRF documents.

g) Ownership of Property. All data, improvements, inventions, technology, and knowledge furnished by SPONSOR pursuant to

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this Agreement or generated or collected in connection with each Study shall constitute the sole property of the SPONSOR.

Section 2. Ongoing Monitoring: The study shall be monitored by SCR or any other Organisation as designated by SPONSOR. Investigator shall facilitate source data verification at the study center by SCR at regular monitoring visits before, during and at the end of the study, and provide the time and necessary data for discussion with the monitor. During these visits the data recorded in the case CRF's used for the study shall be verified at the study center by comparing them with the original data in study participant records and other source documentation. After the check of CRF's for completeness and correctness, Investigator shall furnish any missing information and make necessary corrections.

Section 3. Audits. Investigator shall provide access by authorized personnel of the quality assurance units of SPONSOR or SCR or regulatory authorities in order to conduct audits of the study. Investigator shall be personally available during the time required by the auditor.

Section 4. Confidentiality. Investigator shall execute and deliver a confidential disclosure agreement in the form set forth in Exhibit A.

Section 5. Final Report; Publication. Upon conclusion of the study SPONSOR may, with the assistance of Investigator as required, prepare an integrated final report thereof. SPONSOR shall retain all right of publication of study results and may request the participation of Investigator therein. Investigator will not publish any aspects of Study or Study results without prior written consent of Sponsor.

Section 6. Ethics Committee (EC). SCR shall help Investigator to obtain EC approval of the study and assist with the necessary regulatory procedures at the study site. Investigator shall by notice send to SCR (referencing the study number on the outside of the correspondence)

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Jaipur National University
Jaipur

before the start of the study a current and signed scientific CV of Investigator (and co-investigator, if applicable) and other staff members involved in the study, other documentation as required, and the signed protocol.

Section 7. Payment. All payments made by SCR to Investigator will be made in accordance with the payment schedule in the form set forth in Exhibit C Payments will be made in favor of **Jaipur National University Society For Social Welfare. Account No. 2246002100026759 and IFSC Code-PUNB0224600**,' and sent to **Dr Jaswant Goyal**, Chief Advisor (Medical Sciences), Jaipur National University Institute for Medical Sciences and Research Centre, Agra – Jaipur Road, Near New RTO Office, Jagatpura, Jaipur, Rajasthan 302017

Section 8. Insurance. On behalf of Investigator, SCR shall at all times maintain a policy of insurance sufficient to support its liabilities and potential liabilities herein. A copy of the cover note/ policy shall be provided by SCR to the Investigator.

Section 9. Termination. SPONSOR may upon notice terminate this agreement at any time with or without cause, including for the reason that no study participants have been admitted into the study within four weeks of site initiation provided that SCR (on Sponsor's behalf) shall promptly pay any compensation due to the Investigator.

Section 10. Applicable Law. The Laws of India, excluding its principles of conflict of law, shall govern any litigation brought in respect of this agreement and shall be brought and conducted in Mumbai, India. In case of any dispute arising out of this agreement the same shall be referred for Arbitration under the provisions of Arbitration & Conciliation Act, 1996.

Section 11. Reimbursement. Reimbursement for services performed, as agreed upon, will be passed on by SCR when such reimbursement amounts

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have been received by SCR from the SPONSOR. In the event of any early termination the total sum payable by SCR (received from the SPONSOR), shall be equitably pro-rated for actual work performed and expenses incurred as of the date of termination, with any unexpected funds previously paid to the Investigator being refunded to SCR. In the event of the SPONSOR not being in a position due to any unforeseen event, to reimburse SCR, SCR in turn will not be liable to reimburse the investigator for such amount for which SCR itself has not received the reimbursement.

IN WITNESS WHEREOF this Agreement has been entered into by the parties through their duly authorized agents, effective as of the date last set below.

For Institute,
Jaipur National University Institute for Medical Sciences and Research Centre, Jaipur

Name: **Dr. Sandeep Bakshi**
Title: Chancellor, Jaipur National University
Date: 19 AUG 2019

For SCR,
Spectrum Clinical Research Pvt. Ltd.

Name: **Dr. Viral Shah**
Title: Medical Director
Date: 16/AUG/2019

For Investigator,
Jaipur National University Institute for Medical Sciences and Research Centre, Jaipur

Name: **Dr. Jaswant Goyal**
Title: Principal Investigator
Date: 19 AUG 2019

(Prof. D K Mathur)
Registrar
Jaipur National University
Jaipur

Exhibit A

CONFIDENTIAL DISCLOSURE AGREEMENT

This Confidential Disclosure Agreement (the "Agreement") is made between **Dr. Jaswant Goyal** hereinafter referred to as 'RECIPIENT' with an address at Jaipur National University Institute for Medical Sciences and Research Centre, Jagatpura, Jaipur and **Spectrum Clinical Research Pvt. Ltd.,** hereinafter referred to as 'SCR' with address at 401, 4th Floor, Kshamalaya, 37, New Marine Lines, Mumbai, 400020, India.

Witnesseth

WHEREAS, 'SCR' possesses certain confidential data and Information related to various Compounds under Clinical Evaluation

WHEREAS, it being understood that the SCR and its affiliates, as the case may be, (the "Disclosing Party") wishes to disclose Confidential Information to the 'RECIPIENT' in order to facilitate discussions.

WHEREAS, the 'RECIPIENT' is willing to receive the Confidential Information subject to the terms and conditions set forth below:

NOW, THEREFORE, in consideration of the premises and mutual promises and benefits set forth herein, the parties hereto hereby agree as follows:

1.0 SCR (the Disclosing Party) is willing to disclose Confidential Information to the 'RECIPIENT' on the following terms:

(a) 'RECIPIENT' will receive, maintain, and hold the Confidential Information in strict confidence and will use at least the same level of care in safeguarding it that it uses with its own confidential material of a similar nature;

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(b) 'RECIPIENT' will not disclose the Confidential Information to any third party or utilize the Confidential Information, except as provided herein, without first having obtained Disclosing Party's written consent to such disclosure or utilization;

(c) 'RECIPIENT' may disclose Confidential Information to its employees and to corporate affiliates, to the extent required to evaluate the potential business relationship or fulfill its obligations; and

(d) All obligations under this Agreement will expire Three (3) years after the date of this agreement.

2.0 The obligations set forth herein shall not apply to the Confidential Information to the extent that:

(a) 'RECIPIENT' lawfully had confidential information in its possession prior to the disclosure by the Disclosing Party, and it was not acquired directly or indirectly from Disclosing Party;

(b) is the confidential information generally available to the public, or hereafter, through no act or omission on the part of 'RECIPIENT', it becomes information generally available to the public;

(c) The confidential information corresponds in substance to information furnished to 'RECIPIENT' on a non-confidential basis by a third party having a legal right to do so; but the same cannot be used to affect adversely the future business interest of the parties.

(d) 'RECIPIENT' can demonstrate by competent evidence that it was developed by or for 'RECIPIENT' independently of the disclosure of Confidential Information by Disclosing Party; or

(e) It is required by applicable law or regulation to be disclosed.

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Jaipur

3.0 Neither this Agreement nor any disclosure hereunder shall be deemed, by this implication or otherwise, to vest in 'RECIPIENT' any license or other ownership rights to or under any patents, know-how, or trade secrets.

4.0 With respect to this Agreement, correspondence with the 'RECIPIENT' shall be addressed to **Dr. Jaswant Goyal** at the address set forth above.
Correspondence with SCR shall be addressed to **Dr. Viral Shah** at the address set forth above.

5.0 No failure or delay by Disclosing Party or 'RECIPIENT' in exercising any right, power, or privilege under this Agreement shall act as a waiver thereof. Any amendments or modifications to this Agreement must be in writing and signed by the parties

6.0 This Agreement shall be governed by the laws of India, without giving effect to the conflicts of laws provisions thereof. In case of any dispute arising out of this agreement the same shall be referred for Arbitration under the provisions of Arbitration & Conciliation Act, 1996.

IN WITNESS WHEREOF this Agreement has been entered into by the parties through their duly authorized agents, effective as of the date last set below.

For,
Jaipur National University Institute for Medical Sciences and Research Centre, Jaipur

Name: **Dr. Jaswant Goyal**
Title: Principal Investigator
Date: 19 AUG 2019

For,
Spectrum Clinical Research Pvt. Ltd.

Name: **Dr. Viral Shah**
Title: Medical Director
Date: 16/AUG/2019

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Registrar
Jaipur National University
Jaipur

Exhibit B

Study Team Composition (Names & Roles)

- **Principal Investigator**

  Dr. Jaswant Goyal
  MBBS, MD, MBA

Name of Principal Investigator: Dr. Jaswant Goyal

Signature of Principal Investigator: जसवंत गोयल

Date: 19 AUG 2015

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Jaipur National University
Jaipur

Exhibit C

Budget and Payment Terms

Per patient's sample collection cost will be Rs.100/- (with storage till dispatch of 5ml sample along with Informed Consent & Electronic Medical Record of subjects) & Rs. 20/- for Consumables (Syringes, Needle, Tourniqette, IV Spot, Alcohol Swab etc.)

Terms & Conditions:

1. No infrastructure will be provided by the Sponsor/SCR except centrifuge. Site has to use their available infrastructure [Laptop/desktop, internet connection, fax, cupboard, deep freezer, etc.].
2. Logistic for the sample shipment will be provided by Sponsor/SCR.
3. Payments will be made based on the number of samples sent along with complete ICF and Electronic Medical Records (EMR) to Sponsor/SCR.
4. No payment will be made for the samples received with less volume (<5 ml) and incomplete ICF and incomplete Electronic Medical Records (EMR).
5. All clinical research funding is subject to deduction of all statutory taxes as applicable. A TDS certificate shall be issued in favor of the beneficiary at the end of the financial year.
6. All payments will be made in favor of **Jaipur National University Institute for Society for Social Welfare, Account No.- 2246002100026759 And IFSC Code- PUNB0224600**
7. All invoices shall be addressed to "Spectrum Clinical Research Pvt. Ltd., 401, Kshamalaya, 37 New Marine Lines, Mumbai - 400020".

Scope of Work:

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Jaipur

- Responsibilities of site & Study team members include but is not limited to helping the Investigator in Protocol related procedures, subject recruitment, follow-up,

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coordinating with various agencies, couriers and vendors, Study supplies accountability, maintaining complete documentation for the Study, and being available when the CRA (clinical research associate/monitor) from SCR visits for monitoring visits.

- Responsibility of Investigator include but is not limited to medical examination and per Protocol decision making and subject safety; and discharging other ICH-GCP, Schedule Y driven investigators responsibilities. It is assumed that the duties of Investigator may be delegated to sub-investigator in his or her absence however ultimate responsibility at site remains with the Investigator.

For,
Jaipur National University Institute for Medical Sciences and Research Centre, Jaipur

Name: **Dr. Jaswant Goyal**
Title: Principal Investigator
Date: 19 AUG 2019

For,
Spectrum Clinical Research Pvt. Ltd.

Name: **Dr. Viral Shah**
Title: Medical Director
Date: 16/AUG/2019

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Jaipur National University
Jaipur

UNDERTAKING BY THE INVESTIGATOR

(Appendix VII Schedule Y Rule 122 Drugs and Cosmetics Act. 1945)

1. Full name, address and title of the Principal Investigator (or Investigator(s) when there is no Principal Investigator)

   Dr. Jaswant Goyal, Principal Investigator

   Jaipur National University Institute for Medical Sciences & Research Centre
   Agra - Jaipur Rd, Near New RTO Office,
   Jagatpura, Jaipur, Rajasthan 302017.

2. Name and address of the medical college, hospital or other facility where the clinical trial will be conducted:

   Jaipur National University Institute for Medical Sciences & Research Centre
   Agra - Jaipur Rd, Near New RTO Office,
   Jagatpura, Jaipur, Rajasthan 302017

3. Education, training & experience that qualify the Investigator for the clinical trial (Attach details including Medical Council registration number, and / or any other statement(s) of qualification(s))

   ☒ Curriculum Vitae ☐ Other Statement of Qualifications

4. Name and address of all clinical laboratory facilities to be used in the study.

   Spectrum Healthcare Lab
   5th Floor, Manish Commercial Centre, 216-A,
   Dr. A. B. Road, Worli, Mumbai - 400025

5. Name and address of the Ethics Committee that is responsible for approval and continuing review of the study.

   Institutional Ethics Committee
   Jaipur National University Institute for Medical Sciences & Research Centre
   Jagatpura, Jaipur

6. Names of the other members of the research team (Co- or sub-Investigators) who will be assisting the Investigator in the conduct of the investigation (s).
   - **Dr Ajit Thakur, Asst. Professor- Clinical Research Coordinator**
   - **Dr Saloni Chandalia- Clinical Research Coordinator**
   - **Ms Rashmi Attri- Clinical Research Coordinator**

7. Protocol Title and Study number (if any) of the clinical trial to be conducted by the Investigator.

   SCR/PNS/2019/001: A blood test to provide high quality DNA and/or plasma linkable to clinical information as a resource for the research.

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Jaipur

Commitments:

(i) I have reviewed the clinical protocol and agree that it contains all the necessary information to conduct the study. I will not begin the study until all necessary Ethics Committee and regulatory approvals have been obtained.

(ii) I agree to conduct the study in accordance with the current protocol. I will not implement any deviation from or changes of the protocol without agreement by the Sponsor and prior review and documented approval / favorable opinion from the Ethics Committee of the amendment, except where necessary to eliminate an immediate hazard(s) to the trial Subjects or when the change(s) involved are only logistical or administrative in nature.

(iii) I agree to personally conduct and/or supervise the clinical trial at my site.

(iv) I agree to inform all Subjects that the drugs are being used for investigational purposes and I will ensure that the requirements relating to obtaining informed consent and ethics committee review and approval specified in the GCP guidelines are met.

(v) I agree to report to the Sponsor all adverse experiences that occur in the course of the investigation(s) in accordance with the regulatory and GCP guidelines.

(vi) I have read and understood the information in the Investigator's brochure, including the potential risks and side effects of the drug.

(vii) I agree to ensure that all associates, colleagues and employees assisting in the conduct of the study are suitably qualified and experienced and they have been informed about their obligations in meeting their commitments in the trial.

(viii) I agree to maintain adequate and accurate records and to make those records available for audit / inspection by the Sponsor, Ethics Committee, Licensing Authority or their authorized representatives, in accordance with regulatory and GCP provisions. I will fully cooperate with any study related audit conducted by regulatory officials or authorized representatives of the Sponsor.

(ix) I agree to promptly report to the Ethics Committee all changes in the clinical trial

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activities and all unanticipated problems involving risks to human Subjects or others.

(x) I agree to inform all serious adverse events to the Sponsor, licensing authority as well as the Chairman of Ethics Committee within 24 hrs of their occurrence

(xi) I will maintain confidentiality of the identification of all participating study patients and assure security and confidentiality of study data.

(xii) I agree to comply with all other requirements, guidelines and statutory obligations as applicable to clinical Investigators participating in clinical trials

Signature of Investigator

13 AUG 2015

Date

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Jaipur National University
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PROPOSED BUDGET SHEET

Name of PI	Dr Abhinav Rathi
Site Name	JNU IMSRC
Study Title	A Multicentric, Open Label, Single Arm, Flexible dose, Observational, Phase IV Clinical Trial to assess the Safety and Efficacy of Fixed Dose Combination (FDC) of Betahistine Dihydrochloride 8/16 mg + Domperidone 10/10 mg Tablet in Patients Diagnosed with Symptoms of Vestibular Peripheral Vertigo [Vertigo/Motion Sickness, Nausea, Dizziness, Headache and Vomiting].
Study Protocol Number	WIN/CT/004/BD/2019, VER. NO. 1.0 DATED 05/APR/2019
Particulars	• Total No of Patients: Thirty (30) • Total No of Visit: Six (06) • Total Study Duration: 28 days • Screening Duration: (-2 to -1 days) 2 days • Active Duration: Twenty one (21) days • Follow up Period: Seven (07) days

Remuneration for Principal Investigator (PI) and study Team:

Particulars	Cost Per Patient (INR)	No. of Patients	Amount (INR)	Sub-Total (INR)
Screening visit	300.00X1=300.00	30	9,000.00	81,000.00
Treatment Duration	500.00X4=2000.00	30	60,000.00	
Follow Up	400.00X1=400.00	30	12,000.00	
Total Cost	2,700.00	30	81,000.00	
Study Archival charge (almirah cost)				10,000.00
Lab cost (will be paid as per actual invoice)			A On Actual	
Ethics Committee Charges (as per IEC fees)			B 25,000 + A + B	
Grand Total (INR)				91,000.00
In words: Ninety one thousand rupees Only.			+ Lab Cost	

PAYEE NAME : JAIPUR NATIONAL UNIVERSITY SOCIETY FOR SOCIAL WELFARE

Note:

- Applicable TDS will be deducted.
- Screen failure for maximum of five (05) subjects will be given at a rate of Rs. 300.00 per subject.
- Treatment Drop out charges (based on number of visits made) will be paid for 20% of total randomized patients.
- Number of study subject is subjected to change.

Initials CRO

Initials PI

(Prof. D K Mathur)
Registrar
Jaipur National University
Jaipur

RAHE

PROPOSED BUDGET SHEET

Term of Payments:

- 10% at the time of site initiation.
- 25% at the time of 50% Patient recruitment.
- 30% at the time of 100% Patient recruitment.
- 25% at the time of site closeout.
- 10% after approved by sponsor

For RAHE Life Science	For Entity
Name: _____	Name: Dr Abhinav Rathi
Signature: _____	Signature:
Designation: _____	Designation: Assistant Prof., Pharmacology - ENT
Date: _____	Date: 03/06/2019
Witness' Name: _____	Witness' Name: Dr Jaswant Goyal
Signature: _____	Signature:
Date: _____	Date: 03/06/2019

(Prof. D K Mathur)
Registrar
Jaipur National University
Jaipur

JAIPUR NATIONAL UNIVERSITY HOSPITAL

Initials CRO

Initials PI

RAHE Life Science

BUDGET APPROVAL SHEET

Name of PI	Dr Abhinav Rathi
Site Name	
Study Title	A multi-centric, randomized, double blind, parallel group, active controlled, comparative Phase III clinical trial to evaluate the efficacy and safety of FDC of Bepotastine Besilate 10mg/10mg plus Montelukast Sodium 5mg/10mg Tablet versus Montelukast Sodium 5mg and Montelukast Sodium 10mg tablet in subjects diagnosed with Allergic Rhinitis.
Study Protocol Number	WIN/CT/007/BEP/MON/2018, Version 1.0 Dated 11 JUL 2018
Particulars	• Total No of Patients: Thirty (30) • Total No of Visit: Six (06) • Total Study Duration: Four (04) weeks • Screening Duration: (-3 to-1 days) 3 days • Active Duration: Two (02) weeks • Follow up Period: Two (02) weeks

Remuneration for Principal Investigator (PI) and study Team:

Particulars	Cost Per Patient (INR)	No. of Patients	Amount (INR)	Sub-Total (INR)
Screening visit	700.00X1=700.00	30	21,000.00	1,53,000.00
Treatment Duration	1000.00X3=3000.00	30	90,000.00	
Follow Up	700.00X2=1400.00	30	42,000.00	
Total Cost	5,100.00	30	1,53,000.00	
Study Archival charge (almirah cost)				10,000.00
Lab cost (will be paid as per actual invoice)				
Ethics Committee Charges (as per IEC fees)				
Grand Total (INR)				1,63,000.00
In words: One lakh sixty three thousand rupees Only.				

Note:

- Applicable TDS will be deducted.
- Screen failure for maximum of five (05) subjects will be given at a rate of Rs. 400.00 per subject.
- Treatment Drop out charges (based on number of visits made) will be paid for 20% of total randomized patients.
- Number of study subject is subjected to change.

(Prof. D K Mathur)
Registrar
Jaipur National University
Jaipur

Initials CRO

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RAHE LIFE SCIENCES
Extending Research to Life

PROPOSED BUDGET SHEET

Name of PI	Dr Anubhav Gupta
Site Name	
Study Title	A Multicentric, Open Label, Single Arm, Observational, Phase IV Clinical trial to Evaluate Safety and Efficacy of Fixed Dose Combination (FDC) of Nortriptyline Hydrochloride 10mg + Gabapentin 400mg Tablet BD in Subjects Diagnosed with Neuropathic Pain due to Diabetic Neuropathy or Post Herpetic Neuralgia.
Study Protocol Number	**WIN/ CT/006/NG/2019, VER. NO. 1.0, DATED 02/FEB/2019.**
Particulars	• Total No of Patients — Thirty (30) • Total No of Visit — Five (05) • Total Study Duration — Forty two (42) days • Screening Duration — (-2 to -1 days) 2 days • Active Duration — Forty two (42) days

Remuneration for Principal Investigator (PI) and study Team:

Particulars	Cost Per Patient (INR)	No. of Patients	Amount (INR)	Sub-Total (INR)
Screening visit	300.00X1=300.00	30	9,000.00	69,000.00
Treatment Duration	500.00X4=2000.00	30	60,000.00	
Total Cost	2300.00	30	69,000.00	
Study Archival charge (almirah cost)				10,000.00
Lab cost (will be paid as per actual invoice)				
Ethics Committee Charges (as per IEC fees)				25000
Grand Total (INR)				79,000.00 +25000
In words: Seventy Nine thousand rupees Only.				

Note:

- Applicable TDS will be deducted.
- Screen failure for maximum of five (05) subjects will be given at a rate of Rs. 300.00 per subject.
- Treatment Drop out charges (based on number of visits made) will be paid for 20% of total randomized patients.
- Number of study subject is subjected to change.

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BUDGET APPROVAL SHEET

Name of PI	Dr. Dilip Kumar Sharma
Site Name	JNUIMSRC
Study Title	A Multicentric, Open Label, Non-comparative, Flexible dose, Phase-IV clinical trial to evaluate safety and efficacy of Fixed-Dose Combination (FDC) of Ramipril 2.5/5/10 mg + Cilnidipine 10/10/10 mg capsules in subjects diagnosed with mild to moderate hypertension.
Study Protocol Number	WIN/CT/007/RC/2019, Version 1.0
Particulars	• Total No of Patients: Thirty (30) • Total No of Visit: Six (06) • Total Study Duration: Four (04) weeks • Screening Duration: (-2 to-1 days) 2 days • Active Duration: Two (03) weeks • Follow up Period: One (01) week

Remuneration for Principal Investigator (PI) and study Team:

Particulars	Cost Per Patient (INR)	No. of Patients	Amount (INR)	Sub-Total (INR)
Screening visit	300.00X1=300.00	30	9,000.00	81,000.00
Treatment Duration	500.00X4=2000.00	30	60,000.00	
Follow Up	400.00X1=400.00	30	12,000.00	
Total Cost	2,700.00	30	81,000.00	
Study Archival charge (almirah cost)				10,000.00
Lab cost (will be paid as per actual invoice)			A	On Actuals.
Ethics Committee Charges (as per IEC fees)			B	25,000
Grand Total (INR)				91,000.00 + A + B
In words: **Ninety one thousand rupees Only.**				+ Lab Cost

PAYEE NAME : JAIPUR NATIONAL UNIVERSITY SOCIETY FOR SOCIAL WELFARE

Note:

- Applicable TDS will be deducted.
- Screen failure for maximum of five (05) subjects will be given at a rate of Rs. 400.00 per subject.
- Treatment Drop out charges (based on number of visits made) will be paid for 20% of total randomized patients.
- Number of study subject is subjected to change.

JAIPUR NATIONAL UNIVERSITY HOSPITAL — INSTITUTE FOR MEDICAL SCIENCES AND RESEARCH CENTRE

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(Prof. D K Mathur)
Registrar
Jaipur National University
Jaipur

RAHE

BUDGET APPROVAL SHEET

- Term of Payments:
- 10% at the time of site initiation.
- 25% at the time of 50% Patient recruitment.
- 30% at the time of 100% Patient recruitment.
- 25% at the time of site closeout.
- 10% after approved by sponsor

For RAHE Life Science	For Entity
Name:	Name: Dr. Dilip Kumar Sharma
Signature:	Signature:
Designation:	Designation: Associate Prof., Medicine
Date:	Date: 03/06/2019
Witness' Name:	Witness' Name: Dr. Jaswant Goyal
Signature:	Signature:
Date:	Date: 03/06/2019

(Prof. D K Mathur)
Registrar
Jaipur National University
Jaipur

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INSTITUTE FOR MEDICAL SCIENCES AND RESEARCH CENTRE
JAIPUR

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RAHE Life Science

BUDGET APPROVAL SHEET

Name of PI	Dr Khushboo Barwa
Site Name	Jaipur National University JNSRC
Study Title	A Multicentric, Open Label, Single Arm, Observational, Phase IV Clinical Trial to assess the Safety and Efficacy of Fixed-Dose Combination (FDC) of Chlordiazepoxide 10 mg + Trifluoperazine 1 mg Tablet in Subjects Diagnosed with anxiety disorders.
Study Protocol Number	WIN/CT/003/CT/2019, Version 1.0
Particulars	• Total No of Patients: Thirty (30) • Total No of Visit: Five (05) • Total Study Duration: Five (05) weeks • Screening Duration: (-2 to-1 days) 2 days • Active Duration: Two(02) to Four (04) weeks • Follow up Period: One (01) week

Remuneration for Principal Investigator (PI) and study Team:

Particulars	Cost Per Patient (INR)	No. of Patients	Amount (INR)	Sub-Total (INR)
Screening visit	300.00X1=300.00	30	9,000.00	81,000.00
Treatment Duration	500.00X3=1500.00	30	60,000.00	
Follow Up	400.00X1=400.00	30	12,000.00	
Total Cost	2,200.00	30	81,000.00	
Study Archival charge (almirah cost)				10,000.00
Lab cost (will be paid as per actual invoice)			A. On Actuals	
Ethics Committee Charges (as per IEC fees)			B. 25000	
Grand Total (INR)				91,000.00 + A+B
In words: Ninety one thousand rupees Only.			+ Lab cost	

Payee Name - Jaipur National University Society for Social Welfare

Note:

- Applicable TDS will be deducted.
- Screen failure for maximum of five (05) subjects will be given at a rate of Rs. 300.00 per subject.
- Treatment Drop out charges (based on number of visits made) will be paid for 20% of total randomized patients.
- Number of study subject is subjected to change.

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(Prof. D K Mathur)
Registrar
Jaipur National University
Jaipur

BUDGET APPROVAL SHEET

- Term of Payments:

- 10% at the time of site initiation.
- 25% at the time of 50% Patient recruitment.
- 30% at the time of 100% Patient recruitment.
- 25% at the time of site closeout.
- 10% after approved by sponsor

For RAHE Life Science	For Entity
Name: _____	Name: Dr Khushboo Baid wa
Signature: _____	Signature: Khushbu
Designation: _____	Designation: Assistant Professor
Date: _____	Date: 03/06/2019
Witness' Name: _____	Witness' Name: Dr Jaswant Goyal
Signature: _____	Signature:
Date: _____	Date: 03/06/2019

(Prof. D K Mathur)
Registrar
Jaipur National University
Jaipur

Initials CRO

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BUDGET APPROVAL SHEET

Name of PI	Dr Praveen Mathur
Site Name	JNUIMSRC
Study Title	A Multicentric, Open Label, Single Arm, Observational, Phase IV Clinical Trial to assess the Safety and Efficacy of Fixed-Dose Combination (FDC) of Tramadol Hydrochloride 37.5mg + Paracetamol 325mg + Dicyclomine Hydrochloride 10mg capsule in management of severe acute spasmodic pain.
Study Protocol Number	WIN/CT/005/TPD/2019, Version 1.0
Particulars	• Total No of Patients — Thirty (30) • Total No of Visit — Four (04) • Total Study Duration — Three (03) weeks • Screening Duration — (-2 to-1 days) 2 days • Active Duration — Two (02) weeks • Follow up Period — One (01) week

Remuneration for Principal Investigator (PI) and study Team:

Particulars	Cost Per Patient (INR)	No. of Patients	Amount (INR)	Sub-Total (INR)
Screening visit	300.00X1=300.00	30	9,000.00	51,000.00
Treatment Duration	500.00X2=1000.00	30	30,000.00	
Follow Up	400.00X1=400.00	30	12,000.00	
Total Cost	1,700.00	30	51,000.00	
Study Archival charge (almirah cost)				10,000.00
Lab cost (will be paid as per actual invoice)				A. on Actuals
Ethics Committee Charges (as per IEC fees)				B. 25000
Grand Total (INR)				61,000.00 + A+B
In words: Sixty one thousand rupees Only.				+ Lab Cost.

86000

PAYEE NAME : JAIPUR NATIONAL UNIVERSITY SOCIETY FOR SOCIAL WELFARE

Note:

- Applicable TDS will be deducted.
- Screen failure for maximum of five (05) subjects will be given at a rate of Rs.300.00 per subject.
- Treatment Drop out charges (based on number of visits made) will be paid for 20% of total randomized patients.
- Number of study subject is subjected to change.

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(Prof. D K Mathur)
Registrar
Jaipur National University
Jaipur

JAIPUR NATIONAL UNIVERSITY HOSPITAL — INSTITUTE FOR MEDICAL SCIENCES RESEARCH CENTRE

4/6/19
Initials PI

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BUDGET APPROVAL SHEET

- **Term of Payments:**
- 10% at the time of site initiation.
- 25% at the time of 50% Patient recruitment.
- 30% at the time of 100% Patient recruitment.
- 25% at the time of site closeout.
- 10% after approved by sponsor

For RAHE Life Science	For Entity
Name: _____	Name: Dr. Pisarien Mathur
Signature: _____	Signature: _____
Designation: _____	Designation: Assistant Prof., Surgery
Date: _____	Date: 4/6/19
Witness' Name: _____	Witness' Name: Dr Jaswant Goyal
Signature: _____	Signature: _____
Date: _____	Date: _____

(Prof. D K Mathur)
Registrar
Jaipur National University
Jaipur

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JAGATPURA, JAIPUR

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