# SANTOSH Deemed to be University



3.2.3: Ratio of research projects/clinical trials per teacher funded by government/industries and non-government agencies during the last five years

\*To view document click on page number

To, Date: 14/07/2021

Dr. Jyoti Batra

Dean Research

Santosh Deemed to be University

Subject: Request for research funding

#### Respected Mam,

We have received a request from your side for a research grant to conduct medical/dental research in various departments. We have received your proposals and revert back after review committee's decision.

S.No	Name of the Project	Name of the Principal Investigator
1	Morphometric study of Intratemporal course of facial nerve in relation to pneumatization of temporal bone	Dr Latika Arora
2	A prospective study to investigate the the utility of anthropometric airway parameters as predictors of difficult airway in neonates	Dr Gauresh Singh
3	An observational study to assess different airway assessment methods in predicting difficult laryngoscopy	Dr Suveer Sharma
4	A pilot study to compare Triglyceride glucose (TyG) index with HbA1C as a marker of prediabetes and also with HOMA-IR (Homeostatic model assessment for assessing insulin resistance) as a marker of insulin resistance.	Dr Preeti Sharma
5	A cross sectional study to assess Acute ECG changes during smoking and tobacco chewing	Dr Harshbardhan
6	Knowledge, attitude, and practices of tobacco vendors toward selling tobacco products to young children and adolescents in Ghaziabad	Ms Namrata Soni

**Sharad Ranjan** (Authorized Signatory)

Date: 21/01/2022

To,

Dr. Jyoti Batra

Dean Research

Santosh Deemed to be University

Subject: Approval for research funding

Respected Mam,

I am pleased to inform you I am ready to provide you a grant of INR 8,30,000 towards following projects by your faculty

S.No	Name of the Project	Name of the Principal Investigator	Funds provided (INR in Lakhs)
1	Morphometric study of Intratemporal course of facial nerve in relation to pneumatization of temporal bone	Dr Latika Arora	1.30
2	A prospective study to investigate the the utility of anthropometric airway parameters as predictors of difficult airway in neonates	Dr Gauresh Singh	1.50
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5	A cross sectional study to assess Acute ECG changes during smoking and tobacco chewing	Dr Harshbardhan	0.90
6	Knowledge, attitude, and practices of tobacco vendors toward selling tobacco products to young children and adolescents in Ghaziabad	Ms Namrata Soni	0.80

Please share with me the full proposals within 30 days of receiving this letter. Further, please submit a copy of final project report post completion as well as the outcome/impact of the project.

Thank you and regards.

**Sharad Ranjan** (Authorized Signatory)

- 1. Dr Latika Arora
- 2. Dr Gauresh Singh
- 3. Dr Suveer Sharma
- 4. Dr Preeti Sharma
- 5. Dr Harshbardhan
- 6. Ms Namrata Soni





## भारत सरकार Government of India

## भारतीय विशिष्ट पहचान प्राधिकरण Unique Identification Authority of India

नामांकन क्रमांक / Enrollment No.: 0013/01001/05060

To

शरद रंजन

Sharad Ranjan

○ C/O Vinod Kumar,

C-71, East End Appartments,
Mayur Vihar Phase-1 Extension
VTC: Mayur Vihar,

Mayur Vihar Phase-1 Extension,

PO: Vasundhra Enclave,

Sub District: Preet Vihar, District: East Delhi,

State: Delhi,

PIN Code: 110096, Mobile: 9205374121



MF016250669FI



आपका आधार क्रमांक / Your Aadhaar No. :

3627 1192 9378

मेरा आधार, मेरी पहचान



#### भारत सरकार

Government of India





शरद रंजन Sharad Ranjan

जन्म तिथि / DOB : 21/12/1979

पुरुष / Male

3627 1192 9378

मेरा आधार मेरी पहचान

Page 4 of 335



Plot No.5, IInd Floor, BN Block(W), Central market, Shalimar Bagh, New Delhi-110088

Date: 14/07/2021

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3	A randomized controlled trial to compare 5 different laryngoscope blades in ease of intubation and incidence of dental injury during direct laryngoscopy.	Dr Mahima Lakhanpal
4	Role of Fructose Enriched Foods in Metabolic Syndrome and cardiovascular Diseases.	Dr Juhi Aggarwal
5	Effect of hydroxychloroquine on beta cell function, insulin resistance, and inflammatory markers in type 2 diabetes patients uncontrolled on glimepiride and metformin therapy	Dr Jyoti Batra
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10	The relationship between continuous and long term use of mobile phones and hearing aids among adults	Dr Abhay Kumar Singh
11	A randomized clinical trial to evaluate the Clinical and radiographic success of immediate implants using commercially available bone augmentation materials: A two year follow up study.	Dr SV Singh
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14	A retrospective cohort study to identify clinical characteristics of patients with hypertensive disorders of pregnancy associated with requiring multiple anti-hypertensive medications to optimize blood pressure in the postpartum setting.	Dr Gunjan Gulati Bhagat
15	Manifestations of cardiac myopathy Imaging studies with pathologic correlations	Dr Ashish Kumar Sukla
16	A prospective study to examine the effect of site and shape of scleral incisions for cataract surgery on corneal curvature	Dr Sarita Agrawal
17	A comparative study to assess the lumbar intervertebral disc parameters in patients with chronic low back pain and healthy individuals	Dr Rajeev Anand
18	Efficacy of Cefazolin versus Ceftriaxone for Extremity Open Fracture Management	Dr Amit Dwivedi
19	Awareness, knowledge and perception on Organ donation among students of health care profession	Dr Swati Singh

20	A comparative study on deciduous teeth eruption among infants born after low-risk pregnancy compared to infants diagnosed with intrauterine growth restriction	Dr Natasha Gambhir
21	Epidemiology of Acute Gastroenteritis Caused by Rotavirus Among Children Less than Five Years Old Admitted in a tertiary care center in Northern Indian region	Dr Alka Agrawal
22	Assessment of serum copper and zinc concentrations in North Indian children with overweight and obesity.	Dr K C Aggarwal

Kadambri Educational and Charitable Trust (Authorized Signatory)

Plot No.5, IInd Floor, BN Block(W), Central market, Shalimar Bagh, New Delhi-110088

Date: 11 Jan., 2022

To,

Dr. Jyoti Batra

Dean Research

Santosh Deemed to be University

Subject: Approval for research funding

Respected Madam,

This is in reference to our ongoing discussions on funding research for health sciences projects for your esteemed institution.

I am pleased to inform you that as at Kadambari Educational and Charitable Trust, we are committed to contribute to research and development by providing monetary support, our board has approved a fund of INR 23,10,000/- towards research grant for the following projects.

S.No.	Name of the Project, Clinical Trial, Endowment, Chairs	Name of the Principal Investigator/Co Investigator	Duration of the project	Funds provided (INR in Lakhs)	Department of Principal Investigator/ Co Investigator
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2	A randomised controlled trial to compare Dexmedetomidine and propofol at different sedation depths during drug-induced sleep endoscopy	Dr Anshul Gaur	1.20	12 months	Faculty of Medicine
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4	Role of Fructose Enriched Foods in Metabolic Syndrome and cardiovascular Diseases.	Dr Juhi Aggarwal	0.70	12 months	Faculty of Medicine

5	Effect of hydroxychloroquine on beta cell function, insulin resistance, and inflammatory markers in type 2 diabetes patients uncontrolled on glimepiride and metformin therapy	Dr Jyoti Batra	1.00	24 months	Faculty of Medicine
6	Demographic profile of patients with right ventricular failure admitted in tertiary care center.	Dr Deepika Agarwal	0.60	6 Months	Faculty of Medicine
7	A cross-sectional observational study to assess the perceived effect of increased pricing on smoked tobacco products quit rates	Mr Pradhumn Katara	0.60	6 Months	Faculty of Medicine
8	An In-Vitro Analysis of Root Fracture Strength Using Single File Systems	Dr Shivani Mangal	1.20	24 months	Faculty of Dentistry
9	Incidence and Intensity of Pain Following Endodontic Treatment by Different Instrumentation Techniques in Teeth With Periapical Lesion	Dr Avdesh Sharma	0.60	12 months	Faculty of Dentistry
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11	A randomized clinical trial to evaluate the Clinical and radiographic success of immediate implants using commercially available bone augmentation materials: A two year follow up study.	Dr SV Singh	1.10	12 months	Faculty of Dentistry
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14	A retrospective cohort study to identify clinical characteristics of patients with hypertensive disorders of pregnancy associated with requiring multiple anti-hypertensive medications to optimize blood pressure in the postpartum setting.	Dr Gunjan Gulati Bhagat	0.60	6 Months	Faculty of Medicine
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16	A prospective study to examine the effect of site and shape of scleral incisions for cataract surgery on corneal curvature	Dr Sarita Agrawal	1.40	18 months	Faculty of Medicine

17	A comparative study to assess the lumbar intervertebral disc parameters in patients with chronic low back pain and healthy individuals	Dr Rajeev Anand	0.90	18 months	Faculty of Medicine
18	Efficacy of Cefazolin versus Ceftriaxone for Extremity Open Fracture Management	Dr Amit Dwivedi	0.80	18 months	Faculty of Medicine
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21	Epidemiology of Acute Gastroenteritis Caused by Rotavirus Among Children Less than Five Years Old Admitted in a tertiary care center in Northern Indian region	Dr Alka Agrawal	1.60	18 months	Faculty of Medicine
22	Assessment of serum copper and zinc concentrations in North Indian children with overweight and obesity.	Dr K C Aggarwal	1.40	18 months	Faculty of Medicine

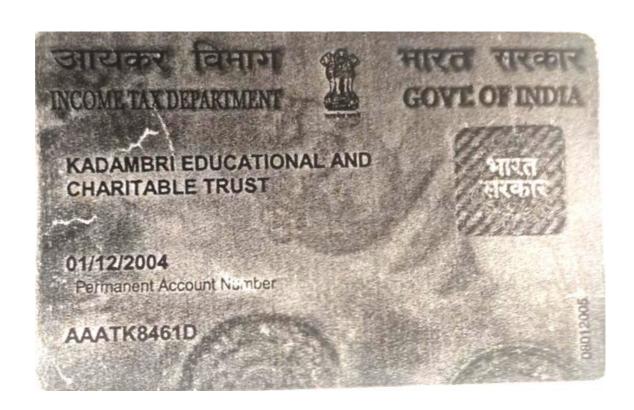


Please share the full proposals within 30 days of receiving this letter. Further, please submit a copy of final project report post completion.

Thank you and regards.

Kadambri Educational and Charitable Trust (Authorized Signatory)

- 1. Dr Vinod Kumar Yadav
- 2. Dr Anshul Gaur
- 3. Dr Mahima Lakhanpal
- 4. Dr Juhi Aggarwal
- 5. Dr Jyoti Batra
- 6. Dr Deepika Agarwal
- 7. Mr Pradhumn Katara
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- 19.Dr Swati Singh
- 20.Dr Natasha Gambhir
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To, Date: 14/07/2021

Dr. Jyoti Batra

Dean Research

Santosh Deemed to be University

Subject: Request for research funding

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6	Knowledge, attitude, and practices of tobacco vendors toward selling tobacco products to young children and adolescents in Ghaziabad	Ms Namrata Soni

**Sharad Ranjan** (Authorized Signatory)

Date: 21/01/2022

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## भारत सरकार Government of India

## भारतीय विशिष्ट पहचान प्राधिकरण Unique Identification Authority of India

नामांकन क्रमांक / Enrollment No.: 0013/01001/05060

To

शरद रंजन

Sharad Ranjan

○ C/O Vinod Kumar,

C-71, East End Appartments,
Mayur Vihar Phase-1 Extension
VTC: Mayur Vihar,

Mayur Vihar Phase-1 Extension,

PO: Vasundhra Enclave,

Sub District: Preet Vihar, District: East Delhi,

State: Delhi,

PIN Code: 110096,

Mobile: 9205374121



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आपका आधार क्रमांक / Your Aadhaar No. :

3627 1192 9378

मेरा आधार, मेरी पहचान



#### भारत सरकार

Government of India





शरद रंजन Sharad Ranjan

जन्म तिथि / DOB : 21/12/1979

पुरुष / Male

3627 1192 9378

मेरा आधार मेरी पहचान

Page 17 of 335



Plot No.5, IInd Floor, BN Block(W), Central market, Shalimar Bagh, New Delhi-110088

Date: 14/07/2021

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Kadambri Educational and Charitable Trust (Authorized Signatory)

Plot No.5, IInd Floor, BN Block(W), Central market, Shalimar Bagh, New Delhi-110088

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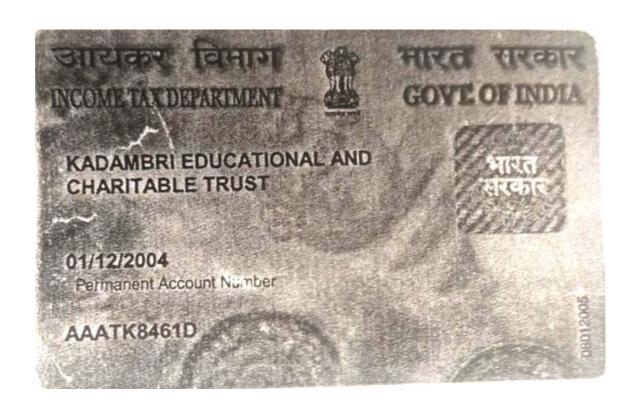


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To, Date: 14/07/2021

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- 1. Dr Latika Arora
- 2. Dr Gauresh Singh
- 3. Dr Suveer Sharma
- 4. Dr Preeti Sharma
- 5. Dr Harshbardhan
- 6. Ms Namrata Soni





## भारत सरकार Government of India

## भारतीय विशिष्ट पहचान प्राधिकरण Unique Identification Authority of India

नामांकन क्रमांक / Enrollment No.: 0013/01001/05060

To

शरद रंजन

Sharad Ranjan

○ C/O Vinod Kumar,

C-71, East End Appartments,
Mayur Vihar Phase-1 Extension
VTC: Mayur Vihar,

Mayur Vihar Phase-1 Extension,

PO: Vasundhra Enclave,

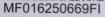
Sub District: Preet Vihar, District: East Delhi,

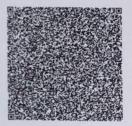
State: Delhi,

PIN Code: 110096,

Mobile: 9205374121







आपका आधार क्रमांक / Your Aadhaar No. :

3627 1192 9378

मेरा आधार, मेरी पहचान



#### भारत सरकार

Government of India





शरद रंजन Sharad Ranjan

जन्म तिथि / DOB : 21/12/1979

पुरुष / Male

3627 1192 9378

मेरा आधार मेरी पहचान

Page 30 of 335



Plot No.5, IInd Floor, BN Block(W), Central market, Shalimar Bagh, New Delhi-110088

Date: 14/07/2021

To,

Dr. Jyoti Batra

Dean Research

Santosh Deemed to be University

Subject: Request for research funding

Respected Mam,

We have received a request from your side for a research grant to conduct medical/dental research in various departments. We have received your proposals and revert after review committee's decision.

S.No.	Name of the Project, Clinical Trial, Endowment, Chairs	Name of the Principal Investigator/Co Investigator
1	A comparison of two doses of palonosetron in the prevention of postoperative nausea vomiting in patients undergoing laparoscopic gynecological surgery.	Dr Vinod Kumar Yadav
2	A randomised controlled trial to compare Dexmedetomidine and propofol at different sedation depths during drug-induced sleep endoscopy	Dr Anshul Gaur
3	A randomized controlled trial to compare 5 different laryngoscope blades in ease of intubation and incidence of dental injury during direct laryngoscopy.	Dr Mahima Lakhanpal
4	Role of Fructose Enriched Foods in Metabolic Syndrome and cardiovascular Diseases.	Dr Juhi Aggarwal
5	Effect of hydroxychloroquine on beta cell function, insulin resistance, and inflammatory markers in type 2 diabetes patients uncontrolled on glimepiride and metformin therapy	Dr Jyoti Batra
6	Demographic profile of patients with right ventricular failure admitted in tertiary care center.	Dr Deepika Agarwal

7	A cross-sectional observational study to assess the perceived effect of increased pricing on smoked tobacco products quit rates	Mr Pradhumn Katara
8	An In-Vitro Analysis of Root Fracture Strength Using Single File Systems	Dr Shivani Mangal
9	Incidence and Intensity of Pain Following Endodontic Treatment by Different Instrumentation Techniques in Teeth With Periapical Lesion	Dr Avdesh Sharma
10	The relationship between continuous and long term use of mobile phones and hearing aids among adults	Dr Abhay Kumar Singh
11	A randomized clinical trial to evaluate the Clinical and radiographic success of immediate implants using commercially available bone augmentation materials: A two year follow up study.	Dr SV Singh
12	Utility of Microbiology Culture in Pediatric Appendicitis to Risk Stratify Patients	Dr Ashutosh Rawat
13	A Randomized controlled trial to investigate the effect of Postoperative Pain on Early Initiation of Breastfeeding and Ambulation After Cesarean Section	Dr Alpana Agrawal
14	A retrospective cohort study to identify clinical characteristics of patients with hypertensive disorders of pregnancy associated with requiring multiple anti-hypertensive medications to optimize blood pressure in the postpartum setting.	Dr Gunjan Gulati Bhagat
15	Manifestations of cardiac myopathy Imaging studies with pathologic correlations	Dr Ashish Kumar Sukla
16	A prospective study to examine the effect of site and shape of scleral incisions for cataract surgery on corneal curvature	Dr Sarita Agrawal
17	A comparative study to assess the lumbar intervertebral disc parameters in patients with chronic low back pain and healthy individuals	Dr Rajeev Anand
18	Efficacy of Cefazolin versus Ceftriaxone for Extremity Open Fracture Management	Dr Amit Dwivedi
19	Awareness, knowledge and perception on Organ donation among students of health care profession	Dr Swati Singh

20	A comparative study on deciduous teeth eruption among infants born after low-risk pregnancy compared to infants diagnosed with intrauterine growth restriction	Dr Natasha Gambhir
21	Epidemiology of Acute Gastroenteritis Caused by Rotavirus Among Children Less than Five Years Old Admitted in a tertiary care center in Northern Indian region	Dr Alka Agrawal
22	Assessment of serum copper and zinc concentrations in North Indian children with overweight and obesity.	Dr K C Aggarwal

Kadambri Educational and Charitable Trust (Authorized Signatory)

Plot No.5, IInd Floor, BN Block(W), Central market, Shalimar Bagh, New Delhi-110088

Date: 11 Jan., 2022

To,

Dr. Jyoti Batra

Dean Research

Santosh Deemed to be University

Subject: Approval for research funding

Respected Madam,

This is in reference to our ongoing discussions on funding research for health sciences projects for your esteemed institution.

I am pleased to inform you that as at Kadambari Educational and Charitable Trust, we are committed to contribute to research and development by providing monetary support, our board has approved a fund of INR 23,10,000/- towards research grant for the following projects.

S.No.	Name of the Project, Clinical Trial, Endowment, Chairs	Name of the Principal Investigator/Co Investigator	Duration of the project	Funds provided (INR in Lakhs)	Department of Principal Investigator/ Co Investigator
1	A comparison of two doses of palonosetron in the prevention of postoperative nausea vomiting in patients undergoing laparoscopic gynecological surgery.	Dr Vinod Kumar Yadav	0.80	12 months	Faculty of Medicine
2	A randomised controlled trial to compare Dexmedetomidine and propofol at different sedation depths during drug-induced sleep endoscopy	Dr Anshul Gaur	1.20	12 months	Faculty of Medicine
3	A randomized controlled trial to compare 5 different laryngoscope blades in ease of intubation and incidence of dental injury during direct laryngoscopy.	Dr Mahima Lakhanpal	1.10	12 months	Faculty of Medicine
4	Role of Fructose Enriched Foods in Metabolic Syndrome and cardiovascular Diseases.	Dr Juhi Aggarwal	0.70	12 months	Faculty of Medicine

5	Effect of hydroxychloroquine on beta cell function, insulin resistance, and inflammatory markers in type 2 diabetes patients uncontrolled on glimepiride and metformin therapy	Dr Jyoti Batra	1.00	24 months	Faculty of Medicine
6	Demographic profile of patients with right ventricular failure admitted in tertiary care center.	Dr Deepika Agarwal	0.60	6 Months	Faculty of Medicine
7	A cross-sectional observational study to assess the perceived effect of increased pricing on smoked tobacco products quit rates	Mr Pradhumn Katara	0.60	6 Months	Faculty of Medicine
8	An In-Vitro Analysis of Root Fracture Strength Using Single File Systems	Dr Shivani Mangal	1.20	24 months	Faculty of Dentistry
9	Incidence and Intensity of Pain Following Endodontic Treatment by Different Instrumentation Techniques in Teeth With Periapical Lesion	Dr Avdesh Sharma	0.60	12 months	Faculty of Dentistry
10	The relationship between continuous and long term use of mobile phones and hearing aids among adults	Dr Abhay Kumar Singh	3.60	24 months	Faculty of Medicine
11	A randomized clinical trial to evaluate the Clinical and radiographic success of immediate implants using commercially available bone augmentation materials: A two year follow up study.	Dr SV Singh	1.10	12 months	Faculty of Dentistry
12	Utility of Microbiology Culture in Pediatric Appendicitis to Risk Stratify Patients	Dr Ashutosh Rawat	0.80	12 months	Faculty of Medicine
13	A Randomized controlled trial to investigate the effect of Postoperative Pain on Early Initiation of Breastfeeding and Ambulation After Cesarean Section	Dr Alpana Agrawal	0.80	12 months	Faculty of Medicine
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17	A comparative study to assess the lumbar intervertebral disc parameters in patients with chronic low back pain and healthy individuals	Dr Rajeev Anand	0.90	18 months	Faculty of Medicine
18	Efficacy of Cefazolin versus Ceftriaxone for Extremity Open Fracture Management	Dr Amit Dwivedi	0.80	18 months	Faculty of Medicine
19	Awareness, knowledge and perception on Organ donation among students of health care profession	Dr Swati Singh	0.60	6 Months	Faculty of Medicine
20	A comparative study on deciduous teeth eruption among infants born after lowrisk pregnancy compared to infants diagnosed with intrauterine growth restriction	Dr Natasha Gambhir	0.50	6 Months	Faculty of Dentistry
21	Epidemiology of Acute Gastroenteritis Caused by Rotavirus Among Children Less than Five Years Old Admitted in a tertiary care center in Northern Indian region	Dr Alka Agrawal	1.60	18 months	Faculty of Medicine
22	Assessment of serum copper and zinc concentrations in North Indian children with overweight and obesity.	Dr K C Aggarwal	1.40	18 months	Faculty of Medicine

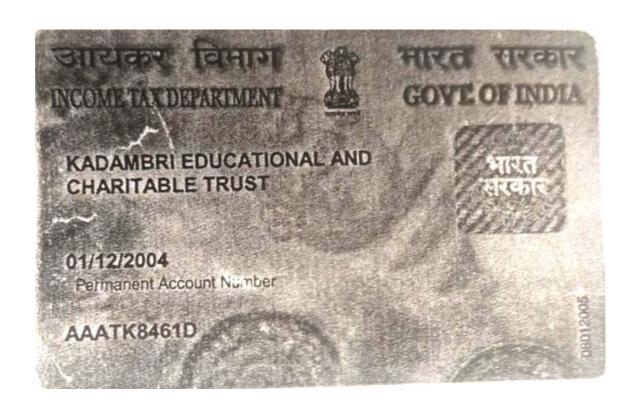


Please share the full proposals within 30 days of receiving this letter. Further, please submit a copy of final project report post completion.

Thank you and regards.

Kadambri Educational and Charitable Trust
(Authorized Signatory)

- 1. Dr Vinod Kumar Yadav
- 2. Dr Anshul Gaur
- 3. Dr Mahima Lakhanpal
- 4. Dr Juhi Aggarwal
- 5. Dr Jyoti Batra
- 6. Dr Deepika Agarwal
- 7. Mr Pradhumn Katara
- 8. Dr Shivani Mangal
- 9. Dr Avdesh Sharma
- 10.Dr Abhay Kumar Singh
- 11.Dr SV Singh
- 12.Dr Ashutosh Rawat
- 13.Dr Alpana Agrawal
- 14.Dr Gunjan Gulati Bhagat
- 15.Dr Ashish Kumar Sukla
- 16.Dr Sarita Agrawal
- 17.Dr Rajeev Anand
- 18.Dr Amit Dwivedi
- 19.Dr Swati Singh
- 20.Dr Natasha Gambhir
- 21.Dr Alka Agrawal
- 22.Dr K C Aggarwal



To, Date: 14/07/2021

Dr. Jyoti Batra

Dean Research

Santosh Deemed to be University

Subject: Request for research funding

### Respected Mam,

We have received a request from your side for a research grant to conduct medical/dental research in various departments. We have received your proposals and revert back after review committee's decision.

S.No	Name of the Project	Name of the Principal Investigator
1	Morphometric study of Intratemporal course of facial nerve in relation to pneumatization of temporal bone	Dr Latika Arora
2	A prospective study to investigate the the utility of anthropometric airway parameters as predictors of difficult airway in neonates	Dr Gauresh Singh
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4	A pilot study to compare Triglyceride glucose (TyG) index with HbA1C as a marker of prediabetes and also with HOMA-IR (Homeostatic model assessment for assessing insulin resistance) as a marker of insulin resistance.	Dr Preeti Sharma
5	A cross sectional study to assess Acute ECG changes during smoking and tobacco chewing	Dr Harshbardhan
6	Knowledge, attitude, and practices of tobacco vendors toward selling tobacco products to young children and adolescents in Ghaziabad	Ms Namrata Soni

**Sharad Ranjan** (Authorized Signatory)

Date: 21/01/2022

To,

Dr. Jyoti Batra

Dean Research

Santosh Deemed to be University

Subject: Approval for research funding

Respected Mam,

I am pleased to inform you I am ready to provide you a grant of INR 8,30,000 towards following projects by your faculty

S.No	Name of the Project	Name of the Principal Investigator	Funds provided (INR in Lakhs)
1	Morphometric study of Intratemporal course of facial nerve in relation to pneumatization of temporal bone	Dr Latika Arora	1.30
2	A prospective study to investigate the the utility of anthropometric airway parameters as predictors of difficult airway in neonates	Dr Gauresh Singh	1.50
3	An observational study to assess different airway assessment methods in predicting difficult laryngoscopy	Dr Suveer Sharma	2.50
4	A pilot study to compare Triglyceride glucose (TyG) index with HbA1C as a marker of prediabetes and also with HOMA-IR (Homeostatic model assessment for assessing insulin resistance) as a marker of insulin resistance.	Dr Preeti Sharma	1.30
5	A cross sectional study to assess Acute ECG changes during smoking and tobacco chewing	Dr Harshbardhan	0.90
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Please share with me the full proposals within 30 days of receiving this letter. Further, please submit a copy of final project report post completion as well as the outcome/impact of the project.

Thank you and regards.

**Sharad Ranjan** (Authorized Signatory)

- 1. Dr Latika Arora
- 2. Dr Gauresh Singh
- 3. Dr Suveer Sharma
- 4. Dr Preeti Sharma
- 5. Dr Harshbardhan
- 6. Ms Namrata Soni





### भारत सरकार Government of India

## भारतीय विशिष्ट पहचान प्राधिकरण Unique Identification Authority of India

नामांकन क्रमांक / Enrollment No.: 0013/01001/05060

To

शरद रंजन

Sharad Ranjan

○ C/O Vinod Kumar,

C-71, East End Appartments,
Mayur Vihar Phase-1 Extension
VTC: Mayur Vihar,

Mayur Vihar Phase-1 Extension,

PO: Vasundhra Enclave,

Sub District: Preet Vihar, District: East Delhi,

State: Delhi,

PIN Code: 110096,

Mobile: 9205374121



MF016250669FI



आपका आधार क्रमांक / Your Aadhaar No. :

3627 1192 9378

मेरा आधार, मेरी पहचान



#### भारत सरकार

Government of India





शरद रंजन Sharad Ranjan

जन्म तिथि / DOB : 21/12/1979

पुरुष / Male

3627 1192 9378

मेरा आधार मेरी पहचान

Page 43 of 335



Plot No.5, IInd Floor, BN Block(W), Central market, Shalimar Bagh, New Delhi-110088

Date: 14/07/2021

To,

Dr. Jyoti Batra

Dean Research

Santosh Deemed to be University

Subject: Request for research funding

Respected Mam,

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Plot No.5, IInd Floor, BN Block(W), Central market, Shalimar Bagh, New Delhi-110088

Date: 11 Jan., 2022

To,

Dr. Jyoti Batra

Dean Research

Santosh Deemed to be University

Subject: Approval for research funding

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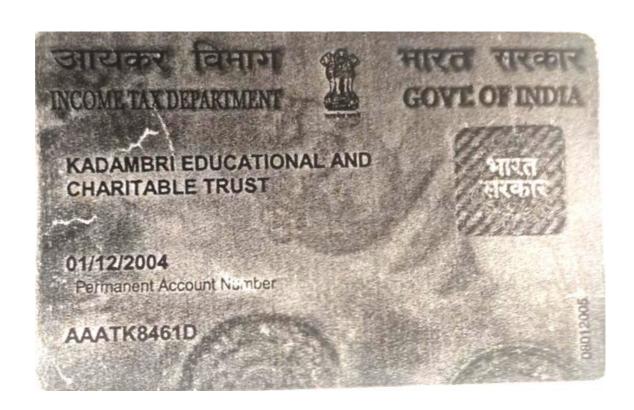


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Kadambri Educational and Charitable Trust
(Authorized Signatory)

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- 3. Dr Mahima Lakhanpal
- 4. Dr Juhi Aggarwal
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- 6. Dr Deepika Agarwal
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- 18.Dr Amit Dwivedi
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- 21.Dr Alka Agrawal
- 22.Dr K C Aggarwal



To, Date: 14/07/2021

Dr. Jyoti Batra

Dean Research

Santosh Deemed to be University

Subject: Request for research funding

### Respected Mam,

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S.No	Name of the Project	Name of the Principal Investigator
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6	Knowledge, attitude, and practices of tobacco vendors toward selling tobacco products to young children and adolescents in Ghaziabad	Ms Namrata Soni

**Sharad Ranjan** (Authorized Signatory)

Date: 21/01/2022

To,

Dr. Jyoti Batra

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Santosh Deemed to be University

Subject: Approval for research funding

Respected Mam,

I am pleased to inform you I am ready to provide you a grant of INR 8,30,000 towards following projects by your faculty

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Please share with me the full proposals within 30 days of receiving this letter. Further, please submit a copy of final project report post completion as well as the outcome/impact of the project.

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**Sharad Ranjan** (Authorized Signatory)

- 1. Dr Latika Arora
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- 6. Ms Namrata Soni





### भारत सरकार Government of India

## भारतीय विशिष्ट पहचान प्राधिकरण Unique Identification Authority of India

नामांकन क्रमांक / Enrollment No.: 0013/01001/05060

To

शरद रंजन

Sharad Ranjan

○ C/O Vinod Kumar,

C-71, East End Appartments,
Mayur Vihar Phase-1 Extension
VTC: Mayur Vihar, Mayur Vihar Phase-1 Extension,

PO: Vasundhra Enclave,

Sub District: Preet Vihar, District: East Delhi,

State: Delhi,

PIN Code: 110096,

Mobile: 9205374121



MF016250669FI



आपका आधार क्रमांक / Your Aadhaar No. :

3627 1192 9378

मेरा आधार, मेरी पहचान



#### भारत सरकार

Government of India





शरद रंजन Sharad Ranjan

जन्म तिथि / DOB : 21/12/1979

पुरुष / Male

3627 1192 9378

मेरा आधार मेरी पहचान

Page 56 of 335



Plot No.5, IInd Floor, BN Block(W), Central market, Shalimar Bagh, New Delhi-110088

Date: 14/07/2021

To,

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Dean Research

Santosh Deemed to be University

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4	Role of Fructose Enriched Foods in Metabolic Syndrome and cardiovascular Diseases.	Dr Juhi Aggarwal
5	Effect of hydroxychloroquine on beta cell function, insulin resistance, and inflammatory markers in type 2 diabetes patients uncontrolled on glimepiride and metformin therapy	Dr Jyoti Batra
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10	The relationship between continuous and long term use of mobile phones and hearing aids among adults	Dr Abhay Kumar Singh
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12	Utility of Microbiology Culture in Pediatric Appendicitis to Risk Stratify Patients	Dr Ashutosh Rawat
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20	A comparative study on deciduous teeth eruption among infants born after low-risk pregnancy compared to infants diagnosed with intrauterine growth restriction	Dr Natasha Gambhir
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22	Assessment of serum copper and zinc concentrations in North Indian children with overweight and obesity.	Dr K C Aggarwal

Plot No.5, IInd Floor, BN Block(W), Central market, Shalimar Bagh, New Delhi-110088

Date: 11 Jan., 2022

To,

Dr. Jyoti Batra

Dean Research

Santosh Deemed to be University

Subject: Approval for research funding

Respected Madam,

This is in reference to our ongoing discussions on funding research for health sciences projects for your esteemed institution.

I am pleased to inform you that as at Kadambari Educational and Charitable Trust, we are committed to contribute to research and development by providing monetary support, our board has approved a fund of INR 23,10,000/- towards research grant for the following projects.

S.No.	Name of the Project, Clinical Trial, Endowment, Chairs	Name of the Principal Investigator/Co Investigator	Duration of the project	Funds provided (INR in Lakhs)	Department of Principal Investigator/ Co Investigator
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3	A randomized controlled trial to compare 5 different laryngoscope blades in ease of intubation and incidence of dental injury during direct laryngoscopy.	Dr Mahima Lakhanpal	1.10	12 months	Faculty of Medicine
4	Role of Fructose Enriched Foods in Metabolic Syndrome and cardiovascular Diseases.	Dr Juhi Aggarwal	0.70	12 months	Faculty of Medicine

5	Effect of hydroxychloroquine on beta cell function, insulin resistance, and inflammatory markers in type 2 diabetes patients uncontrolled on glimepiride and metformin therapy	Dr Jyoti Batra	1.00	24 months	Faculty of Medicine
6	Demographic profile of patients with right ventricular failure admitted in tertiary care center.	Dr Deepika Agarwal	0.60	6 Months	Faculty of Medicine
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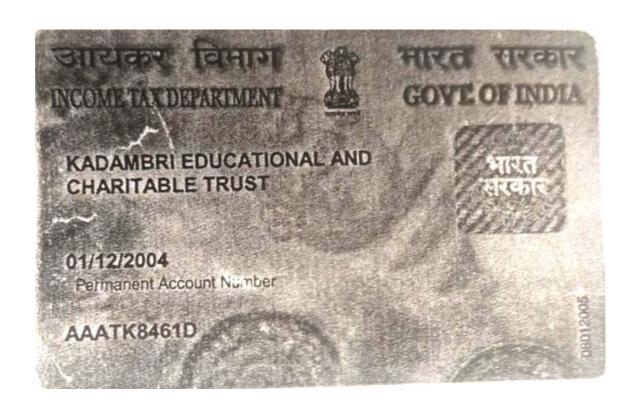


Please share the full proposals within 30 days of receiving this letter. Further, please submit a copy of final project report post completion.

Thank you and regards.

Kadambri Educational and Charitable Trust (Authorized Signatory)

- 1. Dr Vinod Kumar Yadav
- 2. Dr Anshul Gaur
- 3. Dr Mahima Lakhanpal
- 4. Dr Juhi Aggarwal
- 5. Dr Jyoti Batra
- 6. Dr Deepika Agarwal
- 7. Mr Pradhumn Katara
- 8. Dr Shivani Mangal
- 9. Dr Avdesh Sharma
- 10.Dr Abhay Kumar Singh
- 11.Dr SV Singh
- 12.Dr Ashutosh Rawat
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- 16.Dr Sarita Agrawal
- 17.Dr Rajeev Anand
- 18.Dr Amit Dwivedi
- 19.Dr Swati Singh
- 20.Dr Natasha Gambhir
- 21.Dr Alka Agrawal
- 22.Dr K C Aggarwal



Date: 28/07/2021

To,

Dr. Jyoti Batra

Dean Research

Santosh Deemed to be University

Subject: Request for research funding

Respected Mam,

We have received a request from your side for a research grant to conduct medical/dental research in various departments. We have received your proposals and revert back after review committee's decision.

S.No.	Title	Name of Principal investigator
1	A Study on Profile of Poisoning Cases in a Tertiary Care Hospital in Ghaziabad	Dr Shilpa Singh
2	Uncoupling proteins in various gene-environment interaction associated with heavy metal exposure and type 2 Diabetes Mellitus in North Indian Population	Dr Juhi Aggarwal, Dr Jyoti Batra

Rajeev Khanna (Authorized Signatory)

Date: 13/01/2022

To,

Dr. Jyoti Batra

Dean Research

Santosh Deemed to be University

Subject: Approval for research funding

#### Respected Mam,

I am pleased to inform you after thorough discussion with you and your faculty members, I am ready to fund the following research projects worth a sum of INR 60,000.

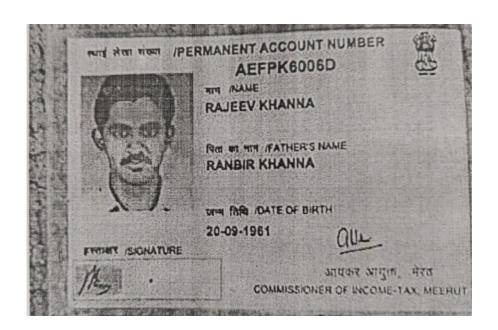
S.No.	Title	Name of Principal investiga tor	Amount (INR in Lakhs)	Study duration
1	A Study on Profile of Poisoning Cases in a Tertiary Care Hospital in Ghaziabad		0.30	6 Months
2	Uncoupling proteins in various gene- environment interaction associated with heavy metal exposure and type 2 Diabetes Mellitus in North Indian Population	Dr Juhi Aggarwal, Dr Jyoti Batra	0.30	3 Months

Please share with me the full proposals within 30 days of receiving this letter. Further, please submit a copy of final project report post completion.

Thank you and regards.

Rajeev Khanna (Authorized Signatory)

- 1. Dr Shilpa Singh
- 2. Dr Juhi Aggarwal, Dr Jyoti Batra





Plot No.5, IInd Floor, BN Block(W), Central market, Shalimar Bagh, New Delhi-110088

Date: 14/07/2021

To,

Dr. Jyoti Batra

Dean Research

Santosh Deemed to be University

Subject: Request for research funding

Respected Mam,

We have received a request from your side for a research grant to conduct medical/dental research in various departments. We have received your proposals and revert after review committee's decision.

S.No.	Name of the Project, Clinical Trial, Endowment, Chairs	Name of the Principal Investigator/Co Investigator
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Kadambri Educational and Charitable Trust (Authorized Signatory)

Plot No.5, IInd Floor, BN Block(W), Central market, Shalimar Bagh, New Delhi-110088

Date: 11 Jan., 2022

To,

Dr. Jyoti Batra

Dean Research

Santosh Deemed to be University

Subject: Approval for research funding

Respected Madam,

This is in reference to our ongoing discussions on funding research for health sciences projects for your esteemed institution.

I am pleased to inform you that as at Kadambari Educational and Charitable Trust, we are committed to contribute to research and development by providing monetary support, our board has approved a fund of INR 23,10,000/- towards research grant for the following projects.

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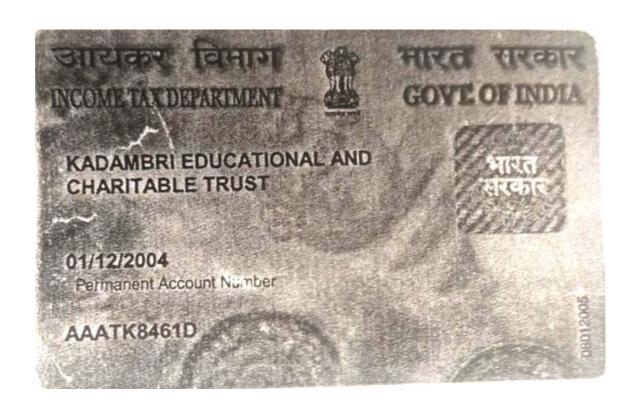


Please share the full proposals within 30 days of receiving this letter. Further, please submit a copy of final project report post completion.

Thank you and regards.

Kadambri Educational and Charitable Trust
(Authorized Signatory)

- 1. Dr Vinod Kumar Yadav
- 2. Dr Anshul Gaur
- 3. Dr Mahima Lakhanpal
- 4. Dr Juhi Aggarwal
- 5. Dr Jyoti Batra
- 6. Dr Deepika Agarwal
- 7. Mr Pradhumn Katara
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- 9. Dr Avdesh Sharma
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- 18.Dr Amit Dwivedi
- 19.Dr Swati Singh
- 20.Dr Natasha Gambhir
- 21.Dr Alka Agrawal
- 22.Dr K C Aggarwal



Date: 11/06/2021

To,

Dr. Jyoti Batra

Dean Research

Santosh Deemed to be University

Subject: Request for research funding

#### Respected Mam,

We have received a request from your side for a research grant to conduct medical/dental research in various departments. We have received your proposals and revert back after review committee's decision.

S.No	Name of the Project, Clinical Trial, Endowment, Chairs	Name of the Principal Investigator/Co Investigator
1	A single blind split mouth study to assess the effect of photobiomodulation on pain during the initial phase of orthodontic treatment	Dr Abhishek Nagpal
2	A study on effect of Omega-3 fatty acids supplements for dry eye syndrome	Dr Sarita Agrawal

Deepak Goyal
(Authorized Signatory)

Date: 07/01/2022

To,

Dr. Jyoti Batra

Dean Research

Santosh Deemed to be University

Subject: Approval for research funding

Respected Mam,

I am pleased to inform you I am ready to provide you a grant of INR 1,50,000 towards following projects by your faculty

Name of the Project, Clinical Trial, Endowment, Chairs	Name of the Principal Investigator/Co Investigator	Department of Principal Investigator/ Co Investigator	Funds provided (INR in Lakhs)	Duration of the project
A single blind split mouth study to assess the effect of photobiomodulation on pain during the initial phase of orthodontic treatment	Dr Abhishek Nagpal	Faculty of Dentistry	1.10	18 months
A study on effect of Omega-3 fatty acids supplements for dry eye syndrome	Dr Sarita Agrawal	Faculty of Medicine	0.40	18 months

Please share with me the full proposals within 30 days of receiving this letter. Further, please submit a copy of final project report post completion as well as the outcome/impact of the project.

Thank you and regards.

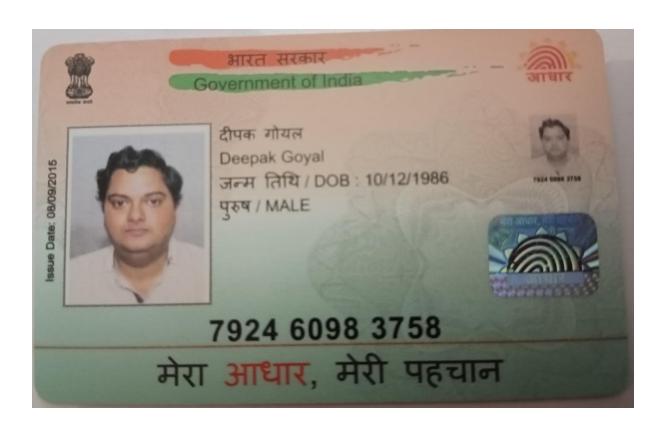
Deepak Goyal
(Authorized Signatory)

CC to:

Dr Abhishek Nagpal

Dr Sarita Agrawal







Plot No.5, IInd Floor, BN Block(W), Central market, Shalimar Bagh, New Delhi-110088

Date: 14/07/2021

To,

Dr. Jyoti Batra

Dean Research

Santosh Deemed to be University

Subject: Request for research funding

Respected Mam,

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Plot No.5, IInd Floor, BN Block(W), Central market, Shalimar Bagh, New Delhi-110088

Date: 11 Jan., 2022

To,

Dr. Jyoti Batra

Dean Research

Santosh Deemed to be University

Subject: Approval for research funding

Respected Madam,

This is in reference to our ongoing discussions on funding research for health sciences projects for your esteemed institution.

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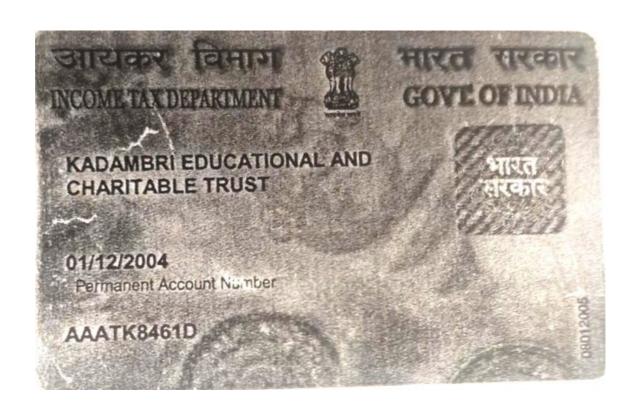


Please share the full proposals within 30 days of receiving this letter. Further, please submit a copy of final project report post completion.

Thank you and regards.

Kadambri Educational and Charitable Trust
(Authorized Signatory)

- 1. Dr Vinod Kumar Yadav
- 2. Dr Anshul Gaur
- 3. Dr Mahima Lakhanpal
- 4. Dr Juhi Aggarwal
- 5. Dr Jyoti Batra
- 6. Dr Deepika Agarwal
- 7. Mr Pradhumn Katara
- 8. Dr Shivani Mangal
- 9. Dr Avdesh Sharma
- 10.Dr Abhay Kumar Singh
- 11.Dr SV Singh
- 12.Dr Ashutosh Rawat
- 13.Dr Alpana Agrawal
- 14.Dr Gunjan Gulati Bhagat
- 15.Dr Ashish Kumar Sukla
- 16.Dr Sarita Agrawal
- 17.Dr Rajeev Anand
- 18.Dr Amit Dwivedi
- 19.Dr Swati Singh
- 20.Dr Natasha Gambhir
- 21.Dr Alka Agrawal
- 22.Dr K C Aggarwal



Date: 14/07/2021

To,

Dr. Jyoti Batra

Dean Research

Santosh Deemed to be University

Subject: Request for research funding

#### Respected Mam,

We have received a request from your side for a research grant to conduct medical/dental research in various departments. We have received your proposals and revert back after review committee's decision.

SNo.	Name of the Project	Name of the Principal Investigator	
1	Cognitive Impairment among the Elderly Population of Ghaziabad and its Association with Smoking, Alcohol Intake and Impairments in Vision, Hearing and Activities of Daily Living	Dr Anupama Singh	
2	A cross-sectional observational study to evaluate Internalized Stigma and Psychiatric Morbidity among Patients with Psoriasis	Dr Ravindra Kumar Bansal	
3	A retropsective study to assess direct bilirubin levels and skeletal muscle weakness in patients with heart failure as prognostic markers for liver failure	Dr Mayurika Tyagi	
4	Prevalence and correlates of bullying perpetration and victimization among school going adolescents in Ghaziabad	Dr Rani Srivastava	
5	Effect of Social Networking Sites on the Quality of Life of College Students in Urban Ghaziabad	Mr Anoop Peter	

Ankit Goyal
(Authorized Signatory)

Date: 30/01/2022

To,

Dr. Jyoti Batra

Dean Research

Santosh Deemed to be University

Subject: Approval for research funding

Respected Mam,

I am pleased to inform you I am ready to provide you a grant of INR 3,90,000 towards following projects by your faculty

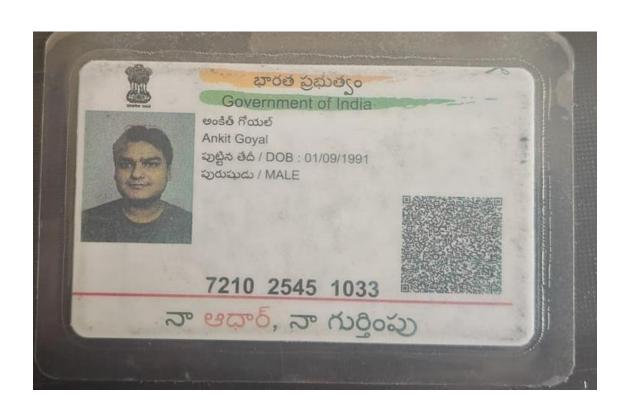
SNo.	Name of the Project	Name of the Principal Investigator	Funds provided (INR in Lakhs)	Duration of the project
1	Cognitive Impairment among the Elderly Population of Ghaziabad and its Association with Smoking, Alcohol Intake and Impairments in Vision, Hearing and Activities of Daily Living	Dr Anupama Singh	0.4	24 months
2	A cross-sectional observational study to evaluate Internalized Stigma and Psychiatric Morbidity among Patients with Psoriasis	Dr Ravindra Kumar Bansal	0.4	24 months
3	A retropsective study to assess direct bilirubin levels and skeletal muscle weakness in patients with heart failure as prognostic markers for liver failure	Dr Mayurika Tyagi	1.1	18 months
4	Prevalence and correlates of bullying perpetration and victimization among school going adolescents in Ghaziabad	Dr Rani Srivastava	1.7	18 months
5	Effect of Social Networking Sites on the Quality of Life of College Students in Urban Ghaziabad	Mr Anoop Peter	0.3	18 months

Please share with me the full proposals within 30 days of receiving this letter. Further, please submit a copy of final project report post completion as well as the outcome/impact of the project.

Thank you and regards.

Ankit Goyal
(Authorized Signatory)

- 1. Dr Anupama Singh
- 2. Dr Ravindra Kumar Bansal
- 3. Dr Mayurika Tyagi
- 4. Dr Rani Srivastava
- 5. Mr Anoop Peter





Plot No.5, IInd Floor, BN Block(W), Central market, Shalimar Bagh, New Delhi-110088

Date: 14/07/2021

To,

Dr. Jyoti Batra

Dean Research

Santosh Deemed to be University

Subject: Request for research funding

Respected Mam,

We have received a request from your side for a research grant to conduct medical/dental research in various departments. We have received your proposals and revert after review committee's decision.

S.No.	Name of the Project, Clinical Trial, Endowment, Chairs	Name of the Principal Investigator/Co Investigator
1	A comparison of two doses of palonosetron in the prevention of postoperative nausea vomiting in patients undergoing laparoscopic gynecological surgery.	Dr Vinod Kumar Yadav
2	A randomised controlled trial to compare Dexmedetomidine and propofol at different sedation depths during drug-induced sleep endoscopy	Dr Anshul Gaur
3	A randomized controlled trial to compare 5 different laryngoscope blades in ease of intubation and incidence of dental injury during direct laryngoscopy.	Dr Mahima Lakhanpal
4	Role of Fructose Enriched Foods in Metabolic Syndrome and cardiovascular Diseases.	Dr Juhi Aggarwal
5	Effect of hydroxychloroquine on beta cell function, insulin resistance, and inflammatory markers in type 2 diabetes patients uncontrolled on glimepiride and metformin therapy	Dr Jyoti Batra
6	Demographic profile of patients with right ventricular failure admitted in tertiary care center.	Dr Deepika Agarwal

7	A cross-sectional observational study to assess the perceived effect of increased pricing on smoked tobacco products quit rates	Mr Pradhumn Katara
8	An In-Vitro Analysis of Root Fracture Strength Using Single File Systems	Dr Shivani Mangal
9	Incidence and Intensity of Pain Following Endodontic Treatment by Different Instrumentation Techniques in Teeth With Periapical Lesion	Dr Avdesh Sharma
10	The relationship between continuous and long term use of mobile phones and hearing aids among adults	Dr Abhay Kumar Singh
11	A randomized clinical trial to evaluate the Clinical and radiographic success of immediate implants using commercially available bone augmentation materials: A two year follow up study.	Dr SV Singh
12	Utility of Microbiology Culture in Pediatric Appendicitis to Risk Stratify Patients	Dr Ashutosh Rawat
13	A Randomized controlled trial to investigate the effect of Postoperative Pain on Early Initiation of Breastfeeding and Ambulation After Cesarean Section	Dr Alpana Agrawal
14	A retrospective cohort study to identify clinical characteristics of patients with hypertensive disorders of pregnancy associated with requiring multiple anti-hypertensive medications to optimize blood pressure in the postpartum setting.	Dr Gunjan Gulati Bhagat
15	Manifestations of cardiac myopathy Imaging studies with pathologic correlations	Dr Ashish Kumar Sukla
16	A prospective study to examine the effect of site and shape of scleral incisions for cataract surgery on corneal curvature	Dr Sarita Agrawal
17	A comparative study to assess the lumbar intervertebral disc parameters in patients with chronic low back pain and healthy individuals	Dr Rajeev Anand
18	Efficacy of Cefazolin versus Ceftriaxone for Extremity Open Fracture Management	Dr Amit Dwivedi
19	Awareness, knowledge and perception on Organ donation among students of health care profession	Dr Swati Singh

20	A comparative study on deciduous teeth eruption among infants born after low-risk pregnancy compared to infants diagnosed with intrauterine growth restriction	Dr Natasha Gambhir
21	Epidemiology of Acute Gastroenteritis Caused by Rotavirus Among Children Less than Five Years Old Admitted in a tertiary care center in Northern Indian region	Dr Alka Agrawal
22	Assessment of serum copper and zinc concentrations in North Indian children with overweight and obesity.	Dr K C Aggarwal

Plot No.5, IInd Floor, BN Block(W), Central market, Shalimar Bagh, New Delhi-110088

Date: 11 Jan., 2022

To,

Dr. Jyoti Batra

Dean Research

Santosh Deemed to be University

Subject: Approval for research funding

Respected Madam,

This is in reference to our ongoing discussions on funding research for health sciences projects for your esteemed institution.

I am pleased to inform you that as at Kadambari Educational and Charitable Trust, we are committed to contribute to research and development by providing monetary support, our board has approved a fund of INR 23,10,000/- towards research grant for the following projects.

S.No.	Name of the Project, Clinical Trial, Endowment, Chairs	Name of the Principal Investigator/Co Investigator	Duration of the project	Funds provided (INR in Lakhs)	Department of Principal Investigator/ Co Investigator
1	A comparison of two doses of palonosetron in the prevention of postoperative nausea vomiting in patients undergoing laparoscopic gynecological surgery.	Dr Vinod Kumar Yadav	0.80	12 months	Faculty of Medicine
2	A randomised controlled trial to compare Dexmedetomidine and propofol at different sedation depths during drug-induced sleep endoscopy	Dr Anshul Gaur	1.20	12 months	Faculty of Medicine
3	A randomized controlled trial to compare 5 different laryngoscope blades in ease of intubation and incidence of dental injury during direct laryngoscopy.	Dr Mahima Lakhanpal	1.10	12 months	Faculty of Medicine
4	Role of Fructose Enriched Foods in Metabolic Syndrome and cardiovascular Diseases.	Dr Juhi Aggarwal	0.70	12 months	Faculty of Medicine

5	Effect of hydroxychloroquine on beta cell function, insulin resistance, and inflammatory markers in type 2 diabetes patients uncontrolled on glimepiride and metformin therapy	Dr Jyoti Batra	1.00	24 months	Faculty of Medicine
6	Demographic profile of patients with right ventricular failure admitted in tertiary care center.	Dr Deepika Agarwal	0.60	6 Months	Faculty of Medicine
7	A cross-sectional observational study to assess the perceived effect of increased pricing on smoked tobacco products quit rates	Mr Pradhumn Katara	0.60	6 Months	Faculty of Medicine
8	An In-Vitro Analysis of Root Fracture Strength Using Single File Systems	Dr Shivani Mangal	1.20	24 months	Faculty of Dentistry
9	Incidence and Intensity of Pain Following Endodontic Treatment by Different Instrumentation Techniques in Teeth With Periapical Lesion	Dr Avdesh Sharma	0.60	12 months	Faculty of Dentistry
10	The relationship between continuous and long term use of mobile phones and hearing aids among adults	Dr Abhay Kumar Singh	3.60	24 months	Faculty of Medicine
11	A randomized clinical trial to evaluate the Clinical and radiographic success of immediate implants using commercially available bone augmentation materials: A two year follow up study.	Dr SV Singh	1.10	12 months	Faculty of Dentistry
12	Utility of Microbiology Culture in Pediatric Appendicitis to Risk Stratify Patients	Dr Ashutosh Rawat	0.80	12 months	Faculty of Medicine
13	A Randomized controlled trial to investigate the effect of Postoperative Pain on Early Initiation of Breastfeeding and Ambulation After Cesarean Section	Dr Alpana Agrawal	0.80	12 months	Faculty of Medicine
14	A retrospective cohort study to identify clinical characteristics of patients with hypertensive disorders of pregnancy associated with requiring multiple anti-hypertensive medications to optimize blood pressure in the postpartum setting.	Dr Gunjan Gulati Bhagat	0.60	6 Months	Faculty of Medicine
15	Manifestations of cardiac myopathy Imaging studies with pathologic correlations	Dr Ashish Kumar Sukla	1.20	18 months	Faculty of Medicine
16	A prospective study to examine the effect of site and shape of scleral incisions for cataract surgery on corneal curvature	Dr Sarita Agrawal	1.40	18 months	Faculty of Medicine

17	A comparative study to assess the lumbar intervertebral disc parameters in patients with chronic low back pain and healthy individuals	Dr Rajeev Anand	0.90	18 months	Faculty of Medicine
18	Efficacy of Cefazolin versus Ceftriaxone for Extremity Open Fracture Management	Dr Amit Dwivedi	0.80	18 months	Faculty of Medicine
19	Awareness, knowledge and perception on Organ donation among students of health care profession	Dr Swati Singh	0.60	6 Months	Faculty of Medicine
20	A comparative study on deciduous teeth eruption among infants born after lowrisk pregnancy compared to infants diagnosed with intrauterine growth restriction	Dr Natasha Gambhir	0.50	6 Months	Faculty of Dentistry
21	Epidemiology of Acute Gastroenteritis Caused by Rotavirus Among Children Less than Five Years Old Admitted in a tertiary care center in Northern Indian region	Dr Alka Agrawal	1.60	18 months	Faculty of Medicine
22	Assessment of serum copper and zinc concentrations in North Indian children with overweight and obesity.	Dr K C Aggarwal	1.40	18 months	Faculty of Medicine

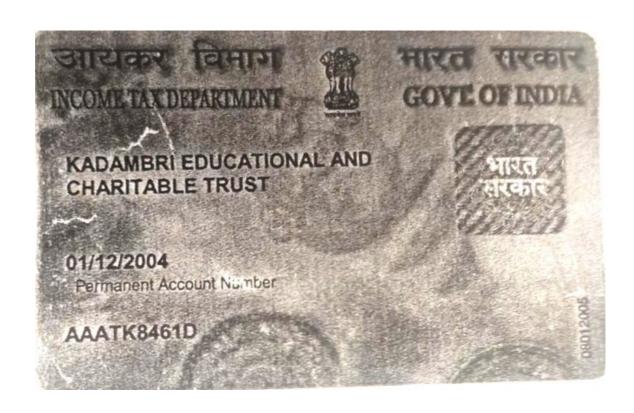


Please share the full proposals within 30 days of receiving this letter. Further, please submit a copy of final project report post completion.

Thank you and regards.

Kadambri Educational and Charitable Trust (Authorized Signatory)

- 1. Dr Vinod Kumar Yadav
- 2. Dr Anshul Gaur
- 3. Dr Mahima Lakhanpal
- 4. Dr Juhi Aggarwal
- 5. Dr Jyoti Batra
- 6. Dr Deepika Agarwal
- 7. Mr Pradhumn Katara
- 8. Dr Shivani Mangal
- 9. Dr Avdesh Sharma
- 10.Dr Abhay Kumar Singh
- 11.Dr SV Singh
- 12.Dr Ashutosh Rawat
- 13.Dr Alpana Agrawal
- 14.Dr Gunjan Gulati Bhagat
- 15.Dr Ashish Kumar Sukla
- 16.Dr Sarita Agrawal
- 17.Dr Rajeev Anand
- 18.Dr Amit Dwivedi
- 19.Dr Swati Singh
- 20.Dr Natasha Gambhir
- 21.Dr Alka Agrawal
- 22.Dr K C Aggarwal



Plot No.5, IInd Floor, BN Block(W), Central market, Shalimar Bagh, New Delhi-110088

Date: 22/07/2021

To,

Dr. Jyoti Batra

Dean Research

Santosh Deemed to be University

Subject: Request for research funding

Respected Mam,

We have received a request from your side for a research grant to conduct medical/dental research in various departments. We have received your proposals and revert after review committee's decision.

S.No.	Name of the Project, Clinical Trial, Endowment, Chairs	Name of the Principal Investigator/Co Investigator
1	Comparison of Blood Pressure Measurements by Currently Available Multiparameter Monitors and Mercury Column Sphygmomanometer in Pediatric Patients Admitted in Intensive Care Unit	Dr Veenu Agrawal
2	An observational study to investigate the association of changes in GS over 1 year and the second (2D) and fourth (4D) digit lengths in young children using the 4D as a covariate	Dr Archana Singh
3	A clinical Dilemma on Ankylosing Spondylitis of Hip Joint in Arthiritis patients	Dr. Amit Dwivedi
4	A qualitative study to assess Oral healthcare-related perception, utilization, and barriers among schoolteachers	Dr Mohit Dadu
5	A Phase III Multicentric, Randomized, doble Blind, Parallel, Group, Comparative, Clinical Study to Evaluate the efficacy and Safety of Bilastine Tablets 40 MG for the Treatemnt of Chronic Spontaneous Urticaria.	Dr V K Garg
6	Cissus Quadrangular is as callus Enhancer -CT Scan based study comparing Patient groups for callus status, Union in Trauma Settings	Dr Amit Dwivedi

7	Prevalence of erosion and its risk factors in school going children of Gautam Budh Nagar	Dr Neeti Mittal, Dr Kush Kalra
8	To evaluate and compare the efficacy of Anorganic bovine bone matrix with Bioactive synthetic Bone graft particulate in treatment of intrabony defects	Dr Priyanka Aggarwal
9	Evaluation of stability of stainless steel and Titanium miniscrew implants used as an anchorage for retraction of maxillary and mandibular anterior teeth - A CBCT study	Dr Akshay Bhargava
10	Comprehensive study of micro debrider assisted endoscopic sinus surgery in CRSwNP.	Dr Raina Rathore
11	Evaluation of Clinical & Microbiological Parameters In Infective Corneal Ulcers	Dr Sarita Agrawal
12	Pathophysiological changes in cord blood & Placenta in hypertensive & anemic pregnant women	Dr Latika Arora
13	Intratympanic steroid therapy for treatment of idiopathic sudden sensory neural hearing loss.	Dr Abhay Kumar Singh
14	Corelation of tear function test and conjunctival impression cytology in dry eye.	Dr Sarita Agrawal
15	Clinicopathological and immunological correlation in viral conjunctivitis.	Dr Yogesh Chander Arora
16	Alzheimer's and Role of Serum Homocysteine Level in its Prognosis	Dr Preeti Sharma, Dr Jyoti Batra
17	Evaluation of Lung Health of the Workers Occupationally Exposed to Petroleum Products	Dr Sanjay Sahai
18	Role of LABA and Ultra-LABA in Asthma Symptom Control	Dr Mahendran. C.S.
19	Incidence, Risk Factors & Outcomes of retinopathy of prematurity in North Indian rural and suburban population	Dr Shikha Pawaiya
20	An investigation of relationship between severe malaria and malnutrition in pediatric age group.	Dr KC Agrawal
21	An obervational study to determine the microbial aetiology and possible risk factors of diarrhoea in children less than five years of age	Dr Virendra Yadav

22	A radiological study on Metacarpal lengths & ratios as a marker of sexual dimorphism in population of Ghaziabad district	Dr Nisha Kaul
23	Effect of Pollution on the oral health in the children of age group 1 to 5 years in Ghaziabad region	Dr. Mohit Dadu

Kadambri Educational and Charitable Trust (Authorized Signatory)

Plot No.5, IInd Floor, BN Block(W), Central market, Shalimar Bagh, New Delhi-110088

Date: 13 Jan., 2022

To,

Dr. Jyoti Batra

Dean Research

Santosh Deemed to be University

Subject: Approval for research funding

Respected Madam,

This is in reference to our ongoing discussions on funding research for health sciences projects for your esteemed institution.

I am pleased to inform you that as at Kadambari Educational and Charitable Trust, we are committed to contribute to research and development by providing monetary support, our board has approved a fund of INR 19,62,000/- towards research grant for the following projects.

S.No.	Name of the Project, Clinical Trial, Endowment, Chairs	Name of the Principal Investigator/Co Investigator	Duration of the project	Funds provided (INR in Lakhs)	Department of Principal Investigator/ Co Investigator
1	Comparison of Blood Pressure Measurements by Currently Available Multiparameter Monitors and Mercury Column Sphygmomanometer in Pediatric Patients Admitted in Intensive Care Unit	Dr Veenu Agrawal	0.40	6 Months	Faculty of Medicine
2	An observational study to investigate the association of changes in GS over 1 year and the second (2D) and fourth (4D) digit lengths in young children using the 4D as a covariate	Dr Archana Singh	1.30	18 months	Faculty of Medicine

3	A clinical Dilemma on Ankylosing Spondylitis of Hip Joint in Arthiritis patients	Dr. Amit Dwivedi	2.20	18 months	Faculty of Medicine
4	A qualitative study to assess Oral healthcare-related perception, utilization, and barriers among schoolteachers	Dr Mohit Dadu	0.40	6 Months	Faculty of Dentistry
5	A Phase III Multicentric, Randomized, doble Blind, Parallel, Group, Comparative, Clinical Study to Evaluate the efficacy and Safety of Bilastine Tablets 40 MG for the Treatemnt of Chronic Spontaneous Urticaria.	Dr V K Garg	0.45	6 Months	Faculty of Medicine
6	Cissus Quadrangular is as callus Enhancer -CT Scan based study comparing Patient groups for callus status, Union in Trauma Settings	Dr Amit Dwivedi	0.25	6 Months	Faculty of Medicine
7	Prevalence of erosion and its risk factors in school going children of Gautam Budh Nagar	Dr Neeti Mittal, Dr Kush Kalra	0.75	12 months	Faculty of Dentistry
8	To evaluate and compare the efficacy of Anorganic bovine bone matrix with Bioactive synthetic Bone graft particulate in treatment of intrabony defects	Dr Priyanka Aggarwal	1.95	12 months	Faculty of Dentistry
9	Evaluation of stability of stainless steel and Titanium miniscrew implants used as an anchorage for retraction of maxillary and mandibular anterior teeth - A CBCT study	Dr Akshay Bhargava	1.62	12 months	Faculty of Dentistry
10	Comprehensive study of micro debrider assisted endoscopic sinus surgery in CRSwNP.	Dr Raina Rathore	0.25	6 Months	Faculty of Medicine
11	Evaluation of Clinical & Microbiological Parameters In Infective Corneal Ulcers	Dr Sarita Agrawal	1.70	18 Months	Faculty of Medicine

12	Pathophysiological changes in cord blood & Placenta in hypertensive & anemic pregnant women	Dr Latika Arora	1.70	6 Months	Faculty of Medicine
13	Intratympanic steroid therapy for treatment of idiopathic sudden sensory neural hearing loss.	Dr Abhay Kumar Singh	0.40	6 Months	Faculty of Medicine
14	Corelation of tear function test and conjunctival impression cytology in dry eye.	Dr Sarita Agrawal	0.40	6 Months	Faculty of Medicine
15	Clinicopathological and immunological correlation in viral conjunctivitis.	Dr Yogesh Chander Arora	0.40	6 Months	Faculty of Medicine
16	Alzheimer's and Role of Serum Homocysteine Level in its Prognosis	Dr Preeti Sharma, Dr Jyoti Batra	0.60	6 Months	Faculty of Medicine
17	Evaluation of Lung Health of the Workers Occupationally Exposed to Petroleum Products	Dr Sanjay Sahai	0.20	6 Months	Faculty of Medicine
18	Role of LABA and Ultra- LABA in Asthma Symptom Control	Dr Mahendran. C.S.	0.40	6 Months	Faculty of Medicine
19	Incidence, Risk Factors & Outcomes of retinopathy of prematurity in North Indian rural and suburban population	Dr Shikha Pawaiya	0.20	6 months	Faculty of Medicine
20	An investigation of relationship between severe malaria and malnutrition in pediatric age group.	Dr KC Agrawal	0.40	6 months	Faculty of Medicine
21	An obervational study to determine the microbial aetiology and possible risk factors of diarrhoea in children less than five years of age	Dr Virendra Yadav	0.25	4 months	Faculty of Medicine
22	A radiological study on Metacarpal lengths & ratios as a marker of sexual dimorphism in population of Ghaziabad district	Dr Nisha Kaul	0.95	12 months	Faculty of Medicine
	•	Page 107 of 335		•	•

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23	Effect of Pollution on the oral health in the children of age group 1 to 5 years in Ghaziabad region	Dr. Mohit Dadu	2.45	12 months	Faculty of Dentistry
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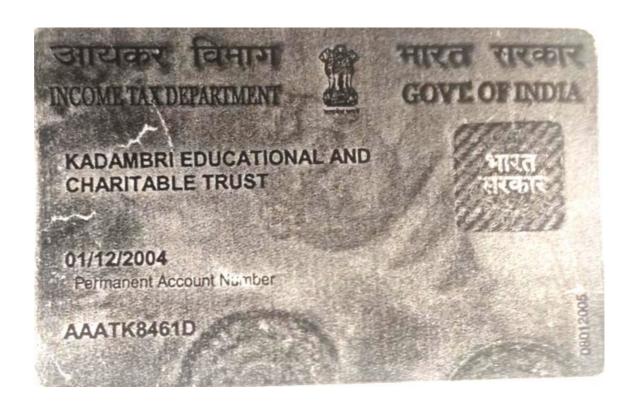
Please share the full proposals within 30 days of receiving this letter. Further, please submit a copy of final project report post completion.

Thank you and regards.

Kadambri Educational and Charitable Trust (Authorized Signatory)

#### CC to:

- 1. Dr Veenu Agrawal
- 2. Dr Archana Singh
- 3. Dr. Amit Dwivedi
- 4. Dr Mohit Dadu
- 5. Dr V K Garg
- 6. Dr Amit Dwivedi
- 7. Dr Neeti Mittal, Dr Kush Kalra
- 8. Dr Priyanka Aggarwal
- 9. Dr Akshay Bhargava
- 10.Dr Raina Rathore
- 11.Dr Sarita Agrawal
- 12.Dr Latika Arora
- 13.Dr Abhay Kumar Singh
- 14.Dr Sarita Agrawal
- 15.Dr Yogesh Chander Arora
- 16.Dr Preeti Sharma, Dr Jyoti Batra
- 17.Dr Sanjay Sahai
- 18.Dr Mahendran. C.S.
- 19.Dr Shikha Pawaiya
- 20.Dr KC Agrawal
- 21.Dr Virendra Yadav
- 22.Dr Nisha Kaul
- 23.Dr. Mohit Dadu



Date: 24/07/2021

To,

Dr. Jyoti Batra

Dean Research

Santosh Deemed to be University

Subject: Request for research funding

Respected Mam,

We have received a request from your side for a research grant to conduct medical/dental research in various departments. We have received your proposals and revert back after review committee's decision.

SNo	Title	Name of Principal investigator
1	A prospective study to investigate the impact of long-term aerobic and combined exercises in modulating hunger, satiety and energy intake in type 2 diabetes mellitus (T2DM).	Dr Rinku Garg

Simerjit Kaur

(Authorized Signatory)

Date: 30/01/2022

To,

Dr. Jyoti Batra

Dean Research

Santosh Deemed to be University

Subject: Approval for research funding

#### Respected Mam,

I am pleased to inform you after thorough discussion with you and your faculty members, I am ready to fund the following research projects worth a sum of INR 1,00,000.

S.No.	Title	Name of Principal investigator	Amount (INR in Lakhs)	Study duration
1.	A prospective study to investigate the impact of long-term aerobic and combined exercises in modulating hunger, satiety and energy intake in type 2 diabetes mellitus (T2DM).	Dr Rinku Garg	1	18 Months

Please share with me the full proposals within 30 days of receiving this letter. Further, please submit a copy of final project report post completion.

Thank you and regards.

PAN: DFLPK8815L

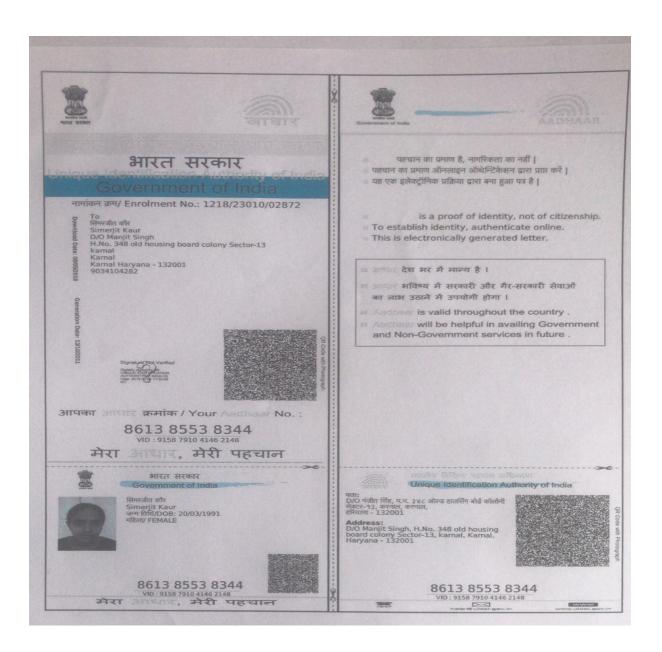
Address: H. No. 348, Old Housing Board Calony, Sector-13, Kaenal. Haryana-132001

Simerjit Kaur

(Authorized Signatory)

CC to:

1. Dr Rinku Garg





Plot No.5, IInd Floor, BN Block(W), Central market, Shalimar Bagh, New Delhi-110088

Date: 22/07/2021

To,

Dr. Jyoti Batra

Dean Research

Santosh Deemed to be University

Subject: Request for research funding

Respected Mam,

We have received a request from your side for a research grant to conduct medical/dental research in various departments. We have received your proposals and revert after review committee's decision.

S.No.	Name of the Project, Clinical Trial, Endowment, Chairs	Name of the Principal Investigator/Co Investigator
1	Comparison of Blood Pressure Measurements by Currently Available Multiparameter Monitors and Mercury Column Sphygmomanometer in Pediatric Patients Admitted in Intensive Care Unit	Dr Veenu Agrawal
2	An observational study to investigate the association of changes in GS over 1 year and the second (2D) and fourth (4D) digit lengths in young children using the 4D as a covariate	Dr Archana Singh
3	A clinical Dilemma on Ankylosing Spondylitis of Hip Joint in Arthiritis patients	Dr. Amit Dwivedi
4	A qualitative study to assess Oral healthcare-related perception, utilization, and barriers among schoolteachers	Dr Mohit Dadu
5	A Phase III Multicentric, Randomized, doble Blind, Parallel, Group, Comparative, Clinical Study to Evaluate the efficacy and Safety of Bilastine Tablets 40 MG for the Treatemnt of Chronic Spontaneous Urticaria.	Dr V K Garg
6	Cissus Quadrangular is as callus Enhancer -CT Scan based study comparing Patient groups for callus status, Union in Trauma Settings	Dr Amit Dwivedi

7	Prevalence of erosion and its risk factors in school going children of Gautam Budh Nagar	Dr Neeti Mittal, Dr Kush Kalra
8	To evaluate and compare the efficacy of Anorganic bovine bone matrix with Bioactive synthetic Bone graft particulate in treatment of intrabony defects	Dr Priyanka Aggarwal
9	Evaluation of stability of stainless steel and Titanium miniscrew implants used as an anchorage for retraction of maxillary and mandibular anterior teeth - A CBCT study	Dr Akshay Bhargava
10	Comprehensive study of micro debrider assisted endoscopic sinus surgery in CRSwNP.	Dr Raina Rathore
11	Evaluation of Clinical & Microbiological Parameters In Infective Corneal Ulcers	Dr Sarita Agrawal
12	Pathophysiological changes in cord blood & Placenta in hypertensive & anemic pregnant women	Dr Latika Arora
13	Intratympanic steroid therapy for treatment of idiopathic sudden sensory neural hearing loss.	Dr Abhay Kumar Singh
14	Corelation of tear function test and conjunctival impression cytology in dry eye.	Dr Sarita Agrawal
15	Clinicopathological and immunological correlation in viral conjunctivitis.	Dr Yogesh Chander Arora
16	Alzheimer's and Role of Serum Homocysteine Level in its Prognosis	Dr Preeti Sharma, Dr Jyoti Batra
17	Evaluation of Lung Health of the Workers Occupationally Exposed to Petroleum Products	Dr Sanjay Sahai
18	Role of LABA and Ultra-LABA in Asthma Symptom Control	Dr Mahendran. C.S.
19	Incidence, Risk Factors & Outcomes of retinopathy of prematurity in North Indian rural and suburban population	Dr Shikha Pawaiya
20	An investigation of relationship between severe malaria and malnutrition in pediatric age group.	Dr KC Agrawal
21	An obervational study to determine the microbial aetiology and possible risk factors of diarrhoea in children less than five years of age	Dr Virendra Yadav

22	A radiological study on Metacarpal lengths & ratios as a marker of sexual dimorphism in population of Ghaziabad district	Dr Nisha Kaul
23	Effect of Pollution on the oral health in the children of age group 1 to 5 years in Ghaziabad region	Dr. Mohit Dadu

Kadambri Educational and Charitable Trust (Authorized Signatory)

Plot No.5, IInd Floor, BN Block(W), Central market, Shalimar Bagh, New Delhi-110088

Date: 13 Jan., 2022

To,

Dr. Jyoti Batra

Dean Research

Santosh Deemed to be University

Subject: Approval for research funding

Respected Madam,

This is in reference to our ongoing discussions on funding research for health sciences projects for your esteemed institution.

I am pleased to inform you that as at Kadambari Educational and Charitable Trust, we are committed to contribute to research and development by providing monetary support, our board has approved a fund of INR 19,62,000/- towards research grant for the following projects.

S.No.	Name of the Project, Clinical Trial, Endowment, Chairs	Name of the Principal Investigator/Co Investigator	Duration of the project	Funds provided (INR in Lakhs)	Department of Principal Investigator/ Co Investigator
1	Comparison of Blood Pressure Measurements by Currently Available Multiparameter Monitors and Mercury Column Sphygmomanometer in Pediatric Patients Admitted in Intensive Care Unit	Dr Veenu Agrawal	0.40	6 Months	Faculty of Medicine
2	An observational study to investigate the association of changes in GS over 1 year and the second (2D) and fourth (4D) digit lengths in young children using the 4D as a covariate	Dr Archana Singh	1.30	18 months	Faculty of Medicine

3	A clinical Dilemma on Ankylosing Spondylitis of Hip Joint in Arthiritis patients	Dr. Amit Dwivedi	2.20	18 months	Faculty of Medicine
4	A qualitative study to assess Oral healthcare-related perception, utilization, and barriers among schoolteachers	Dr Mohit Dadu	0.40	6 Months	Faculty of Dentistry
5	A Phase III Multicentric, Randomized, doble Blind, Parallel, Group, Comparative, Clinical Study to Evaluate the efficacy and Safety of Bilastine Tablets 40 MG for the Treatemnt of Chronic Spontaneous Urticaria.	Dr V K Garg	0.45	6 Months	Faculty of Medicine
6	Cissus Quadrangular is as callus Enhancer -CT Scan based study comparing Patient groups for callus status, Union in Trauma Settings	Dr Amit Dwivedi	0.25	6 Months	Faculty of Medicine
7	Prevalence of erosion and its risk factors in school going children of Gautam Budh Nagar	Dr Neeti Mittal, Dr Kush Kalra	0.75	12 months	Faculty of Dentistry
8	To evaluate and compare the efficacy of Anorganic bovine bone matrix with Bioactive synthetic Bone graft particulate in treatment of intrabony defects	Dr Priyanka Aggarwal	1.95	12 months	Faculty of Dentistry
9	Evaluation of stability of stainless steel and Titanium miniscrew implants used as an anchorage for retraction of maxillary and mandibular anterior teeth - A CBCT study	Dr Akshay Bhargava	1.62	12 months	Faculty of Dentistry
10	Comprehensive study of micro debrider assisted endoscopic sinus surgery in CRSwNP.	Dr Raina Rathore	0.25	6 Months	Faculty of Medicine
11	Evaluation of Clinical & Microbiological Parameters In Infective Corneal Ulcers	Dr Sarita Agrawal	1.70	18 Months	Faculty of Medicine

12	Pathophysiological changes in cord blood & Placenta in hypertensive & anemic pregnant women	Dr Latika Arora	1.70	6 Months	Faculty of Medicine
13	Intratympanic steroid therapy for treatment of idiopathic sudden sensory neural hearing loss.	Dr Abhay Kumar Singh	0.40	6 Months	Faculty of Medicine
14	Corelation of tear function test and conjunctival impression cytology in dry eye.	Dr Sarita Agrawal	0.40	6 Months	Faculty of Medicine
15	Clinicopathological and immunological correlation in viral conjunctivitis.	Dr Yogesh Chander Arora	0.40	6 Months	Faculty of Medicine
16	Alzheimer's and Role of Serum Homocysteine Level in its Prognosis	Dr Preeti Sharma, Dr Jyoti Batra	0.60	6 Months	Faculty of Medicine
17	Evaluation of Lung Health of the Workers Occupationally Exposed to Petroleum Products	Dr Sanjay Sahai	0.20	6 Months	Faculty of Medicine
18	Role of LABA and Ultra- LABA in Asthma Symptom Control	Dr Mahendran. C.S.	0.40	6 Months	Faculty of Medicine
19	Incidence, Risk Factors & Outcomes of retinopathy of prematurity in North Indian rural and suburban population	Dr Shikha Pawaiya	0.20	6 months	Faculty of Medicine
20	An investigation of relationship between severe malaria and malnutrition in pediatric age group.	Dr KC Agrawal	0.40	6 months	Faculty of Medicine
21	An obervational study to determine the microbial aetiology and possible risk factors of diarrhoea in children less than five years of age	Dr Virendra Yadav	0.25	4 months	Faculty of Medicine
22	A radiological study on Metacarpal lengths & ratios as a marker of sexual dimorphism in population of Ghaziabad district	Dr Nisha Kaul	0.95	12 months	Faculty of Medicine

Page 118 of 335

23	Effect of Pollution on the oral health in the children of age group 1 to 5 years in Ghaziabad region	Dr. Mohit Dadu	2.45	12 months	Faculty of Dentistry
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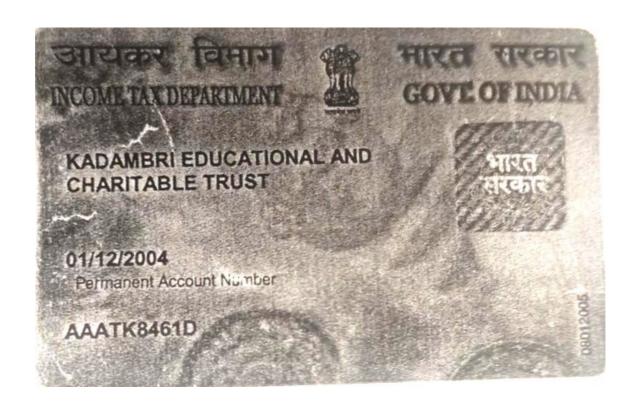
Please share the full proposals within 30 days of receiving this letter. Further, please submit a copy of final project report post completion.

Thank you and regards.

Kadambri Educational and Charitable Trust (Authorized Signatory)

#### CC to:

- 1. Dr Veenu Agrawal
- 2. Dr Archana Singh
- 3. Dr. Amit Dwivedi
- 4. Dr Mohit Dadu
- 5. Dr V K Garg
- 6. Dr Amit Dwivedi
- 7. Dr Neeti Mittal, Dr Kush Kalra
- 8. Dr Priyanka Aggarwal
- 9. Dr Akshay Bhargava
- 10.Dr Raina Rathore
- 11.Dr Sarita Agrawal
- 12.Dr Latika Arora
- 13.Dr Abhay Kumar Singh
- 14.Dr Sarita Agrawal
- 15.Dr Yogesh Chander Arora
- 16.Dr Preeti Sharma, Dr Jyoti Batra
- 17.Dr Sanjay Sahai
- 18.Dr Mahendran. C.S.
- 19.Dr Shikha Pawaiya
- 20.Dr KC Agrawal
- 21.Dr Virendra Yadav
- 22.Dr Nisha Kaul
- 23.Dr. Mohit Dadu



Date: 14/07/2021

To,

Dr. Jyoti Batra

Dean Research

Santosh Deemed to be University

Subject: Request for research funding

Respected Mam,

We have received a request from your side for a research grant to conduct medical/dental research in various departments. We have received your proposals and revert back after review committee's decision.

S.No	Name of the Project	Name of the Principal Investigator
1	A cross-sectional observational study to assess the impact of psychiatric comorbidity on adherence to anti tubercular treatment in a northern Indian region	Dr Mahendran. C.S.
2	A randomized controlled trial to assess and compare self-reported tobacco quit status and biochemically verified cotinine levels among TB patients using two tobacco cessation methods	Dr Prachi Saxena

Jashret Singh

Jaspreet Singh (Authorized Signatory)

Date: 07/01/2022

To,

Dr. Jyoti Batra

Dean Research

Santosh Deemed to be University

Subject: Request for research funding

Respected Mam,

I am pleased to inform you I am ready to provide you a grant of INR 1,50,000 towards following projects by your faculty.

S.No	Name of the Project	Name of the Principal Investigator	Funds provided (INR in Lakhs)	Duration of Project
1	A cross-sectional observational study to assess the impact of psychiatric co-morbidity on adherence to anti tubercular treatment in a northern Indian region	Dr Mahendran C.S.	0.40	6 Months
2	A randomized controlled trial to assess and compare self-reported tobacco quit status and biochemically verified cotinine levels among TB patients using two tobacco cessation methods	Dr Prachi Saxena	1.10	18 months

Please share with me the full proposals within 30 days of receiving this letter. Further, please submit a copy of final project report post completion as well as the outcome/impact of the project.

Thank you and regards.

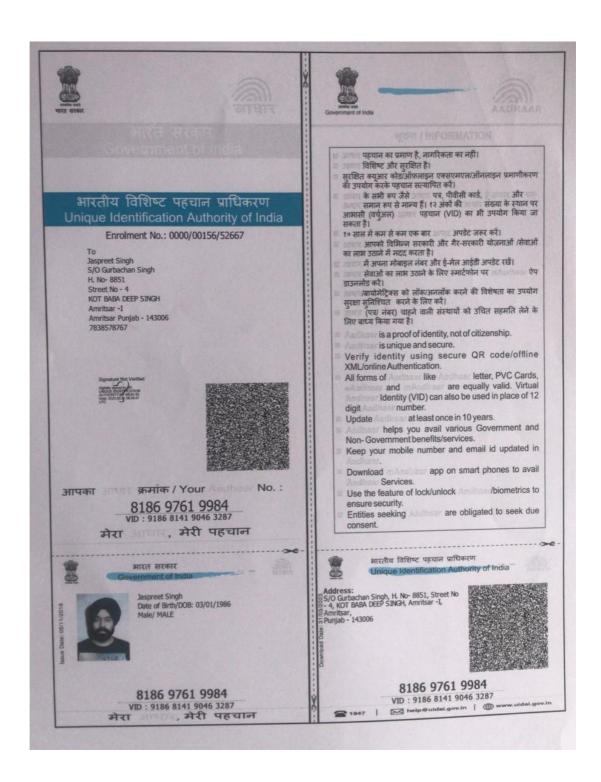
CC to:

1. Dr Mahendran C.S.

2. Dr Prachi Saxena

Jashret Sigh

Jaspreet Singh (Authorized Signatory)





Plot No.5, IInd Floor, BN Block(W), Central market, Shalimar Bagh, New Delhi-110088

Date: 22/07/2021

To,

Dr. Jyoti Batra

Dean Research

Santosh Deemed to be University

Subject: Request for research funding

Respected Mam,

We have received a request from your side for a research grant to conduct medical/dental research in various departments. We have received your proposals and revert after review committee's decision.

S.No.	Name of the Project, Clinical Trial, Endowment, Chairs	Name of the Principal Investigator/Co Investigator
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22	A radiological study on Metacarpal lengths & ratios as a marker of sexual dimorphism in population of Ghaziabad district	Dr Nisha Kaul
23	Effect of Pollution on the oral health in the children of age group 1 to 5 years in Ghaziabad region	Dr. Mohit Dadu

Kadambri Educational and Charitable Trust (Authorized Signatory)

Plot No.5, IInd Floor, BN Block(W), Central market, Shalimar Bagh, New Delhi-110088

Date: 13 Jan., 2022

To,

Dr. Jyoti Batra

Dean Research

Santosh Deemed to be University

Subject: Approval for research funding

Respected Madam,

This is in reference to our ongoing discussions on funding research for health sciences projects for your esteemed institution.

I am pleased to inform you that as at Kadambari Educational and Charitable Trust, we are committed to contribute to research and development by providing monetary support, our board has approved a fund of INR 19,62,000/- towards research grant for the following projects.

S.No.	Name of the Project, Clinical Trial, Endowment, Chairs	Name of the Principal Investigator/Co Investigator	Duration of the project	Funds provided (INR in Lakhs)	Department of Principal Investigator/ Co Investigator
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Page 130 of 335

23	Effect of Pollution on the oral health in the children of age group 1 to 5 years in Ghaziabad region	Dr. Mohit Dadu	2.45	12 months	Faculty of Dentistry
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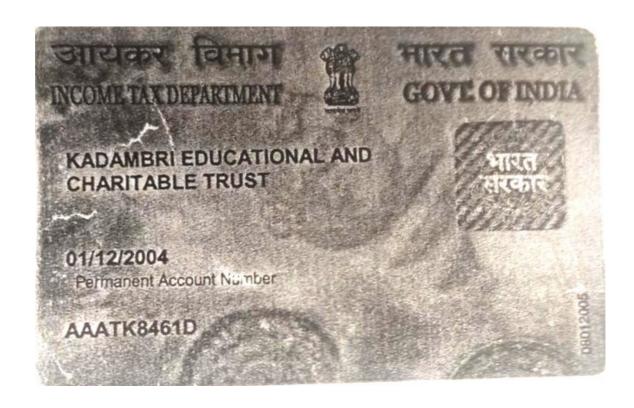
Please share the full proposals within 30 days of receiving this letter. Further, please submit a copy of final project report post completion.

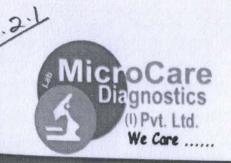
Thank you and regards.

Kadambri Educational and Charitable Trust (Authorized Signatory)

#### CC to:

- 1. Dr Veenu Agrawal
- 2. Dr Archana Singh
- 3. Dr. Amit Dwivedi
- 4. Dr Mohit Dadu
- 5. Dr V K Garg
- 6. Dr Amit Dwivedi
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- 21.Dr Virendra Yadav
- 22.Dr Nisha Kaul
- 23.Dr. Mohit Dadu





## Lab MICROCARE DIAGNOSTICS INDIA PRIVATE LIMITED

A 1 Shiv Park School Road, Khanpur, New Delhi - 110062 Ph.: 9810400063, 9958368063 Web: www.microcarediagnostic.com

NOV 2021

To

Dr. Shaktibala Dutta

Prof and HOD Pharmacology

Santosh medical college, Santosh deemed to be university

Ghaziabad NCR

Dear doctor

We are pleased to inform you that following a thorough examination of your project as below

Title	Department	Principal investigator	Amount
1. To assess the efficacy of covid-19 vaccine administered by changes in antibody titre levels of persons vaccinated under vaccination program by Government of India, MOHFW at tertiary care teaching Centre in National Capital Region of India	Pharmacology	Dr. S.B.Dutta	75000/-

Against the above projects, consumables worth Rs.75000 (seventy-five thousands) supplied to the department/college. Please send us a detailed report on your result after the assignment is complete.

Best regards & thank you for your time & attention

#### Copy to:

- 1. Academic section
- 2. Dean research office

From





Plot No.5, IInd Floor, BN Block(W), Central market, Shalimar Bagh, New Delhi-110088

Date: 22/07/2021

To,

Dr. Jyoti Batra

Dean Research

Santosh Deemed to be University

Subject: Request for research funding

Respected Mam,

We have received a request from your side for a research grant to conduct medical/dental research in various departments. We have received your proposals and revert after review committee's decision.

S.No.	Name of the Project, Clinical Trial, Endowment, Chairs	Name of the Principal Investigator/Co Investigator
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23	Effect of Pollution on the oral health in the children of age group 1 to 5 years in Ghaziabad region	Dr. Mohit Dadu

Kadambri Educational and Charitable Trust (Authorized Signatory)

Plot No.5, IInd Floor, BN Block(W), Central market, Shalimar Bagh, New Delhi-110088

Date: 13 Jan., 2022

To,

Dr. Jyoti Batra

Dean Research

Santosh Deemed to be University

Subject: Approval for research funding

Respected Madam,

This is in reference to our ongoing discussions on funding research for health sciences projects for your esteemed institution.

I am pleased to inform you that as at Kadambari Educational and Charitable Trust, we are committed to contribute to research and development by providing monetary support, our board has approved a fund of INR 19,62,000/- towards research grant for the following projects.

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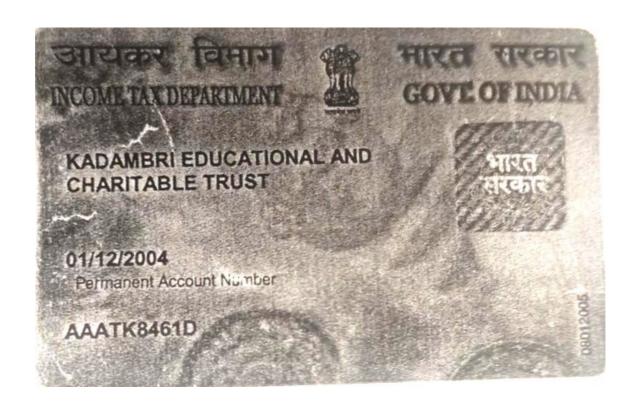
Please share the full proposals within 30 days of receiving this letter. Further, please submit a copy of final project report post completion.

Thank you and regards.

Kadambri Educational and Charitable Trust (Authorized Signatory)

#### CC to:

- 1. Dr Veenu Agrawal
- 2. Dr Archana Singh
- 3. Dr. Amit Dwivedi
- 4. Dr Mohit Dadu
- 5. Dr V K Garg
- 6. Dr Amit Dwivedi
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- 20.Dr KC Agrawal
- 21.Dr Virendra Yadav
- 22.Dr Nisha Kaul
- 23.Dr. Mohit Dadu



Date: 20/08/2021

To,

Dr. Jyoti Batra

Dean Research

Santosh Deemed to be University

Subject: Request for research funding

#### Respected Mam,

We have received a request from your side for a research grant to conduct medical/dental research in various departments. We have received your proposals and revert back after review committee's decision.

S.No	Name of the Project, Clinical Trial, Endowment, Chairs	Name of the Principal Investigator	
1	Pattern of caries in adolescents	Dr. Mohit Dadu	
2	A Comparative Assessment of the Upper Pharyngeal Airway Dimensions in different facial types : a cephalometric study	Dr Tina Chugh	
3	A randomized controlled trial to comparatively evaluate the effect of Silver diamine fluoride and Fluoride varnish on preventing new carious lesions in children with high caries risk	Dr Nidhi Gupta	
4	To compare and evaluate the primary and secondary implant stability between calcium phosphate surface coated implants and alumina blasted/acid etched implants using resonance frequency analysis.	Dr Shweta Bali	

Dheraj Mehra (Authorized Signatory)

Date: 04/02/2022

To,

Dr. Jyoti Batra

Dean Research

Santosh Deemed to be University

Subject: Approval for research funding

Respected Mam,

I am pleased to inform you I am ready to provide you a grant of INR 4,00,000 towards following projects by your faculty  $\frac{1}{2}$ 

S.No	Name of the Project	Name of the Principal Investigator/Co Investigator	Funds provided (INR in Lakhs)	Duration of the project	
1	Pattern of caries in adolescents	Dr. Mohit Dadu	0.40	6 months	
2	A Comparative Assessment of the Upper Pharyngeal Airway Dimensions in different facial types: a cephalometric study	Dr Tina Chugh	a Chugh 0.80		
3	A randomized controlled trial to comparatively evaluate the effect of Silver diamine fluoride and Fluoride varnish on preventing new carious lesions in children with high caries risk	Dr Nidhi Gupta	1.25	9 months	
4	To compare and evaluate the primary and secondary implant stability between calcium phosphate surface coated implants and alumina blasted/acid etched implants using resonance frequency analysis.	Dr Shweta Bali	1.55	6 months	

Please share with me the full proposals within 30 days of receiving this letter. Further, please submit a copy of final project report post completion as well as the outcome/impact of the project.

Thank you and regards.

Dheeraj Hehra
(Authorized Signatory)

CC to:

- 1. Dr. Mohit Dadu
- 2. Dr Tina Chugh
- 3. Dr Nidhi Gupta
- 4. Dr Shweta Bali



### A-905, Omicron-1, Greater Noida, Uttar Pradesh - 201308

Ref. No.:-SF/JUL/19/2021 Date:-19/07/2021

## Research Grant Project Approval Letter

Dr. Parvinder Kaur, Professor Orthodontics Santosh Dental College and Hospital Santosh Deemed to be University Ghaziabad, U.P.

Subject: Sanctioning of Research Project Grant

Dear Dr.Parvinder Kaur,

We are pleased to inform you that your application regarding approval of funding grant for the Research project titled "Prevalence of congenitally missing teeth in permanent dentition in Delhi NCR region" for 12 months has been considered for funding grants by our Expert Committee after review.

The above said project is hereby approved by the Competent Authority and sanctioned a total amount of Rs.9,000/- (Nine Thousand Only).

Foundation

Thank You and Regards

Jovery

(Authorized Signatory)

#### CC to:

- 1) Dean Research, Santosh University, Ghaziabad, UP
- 2) Office copy

Date: 21/06/2021

To,

Dr. Jyoti Batra

Dean Research

Santosh Deemed to be University

Subject: Request for research funding

Respected Mam,

We have received a request from your side for a research grant to conduct medical/dental research in various departments. We have received your proposals and revert back after review committee's decision.

S.No.	Title	Name of Principal investigator
1.	Oral Health related quality of life among School going Children in District Ghaziabad	Dr Mohit Dadu
2.	Prevalence of TMJ disorders in the local population of Ghaziabad City	Dr Chandni Batra
3.	Study of Histopathological Changes in Placenta In Pre-Eclampsia/Eclampsia	Dr Mayurika Tyagi
4.	Analyzing serum IL-6 in Oral Squamous Cell Carcinoma as a diagnostic marker	Dr Neeraj Grover

Mrs. Sheetal Rawat

(Authorized Signatory)

Date: 30/01/2022

To,

Dr. Jyoti Batra

Dean Research

Santosh Deemed to be University

Subject: Approval for research funding

Respected Mam,

I am pleased to inform you after thorough discussion with you and your faculty members, I am ready to fund the following research projects worth a sum of INR 5,00,000.

S.No.	Title	Name of Principal investigator	Amount (INR in Lakhs)	Study duration
1.	Oral Health related quality of life among School going Children in District Ghaziabad	Dr Mohit Dadu	0.90	18 months
2.	Prevalence of TMJ disorders in the local population of Ghaziabad City	Dr Chandni Batra	1.25	18 months
3.	Study of Histopathological Changes in Placenta In Pre- Eclampsia/Eclampsia	Dr Mayurika Tyagi	1.70	12 months
4.	Analyzing serum IL-6 in Oral Squamous Cell Carcinoma as a diagnostic marker	Dr Neeraj Grover	1.15	18 months

Please share with me the full proposals within 30 days of receiving this letter. Further, please submit a copy of final project report post completion.

Thank you and regards.

CC to:

1. Dr Mohit Dadu

2. Dr Chandni Batra

3. Dr Mayurika Tyagi

4. Dr Shweta Bali

Mrs. Sheetal Rawat

(Authorized Signatory)







Mob: 9810612151

Email: purnimasci@yahoo.com



# Purnima Scientific Traders

#### **Authorized stockiest for:**

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568(540/511), SADDIQ NAGAR, NOOR NAGAR, BESIDE CHSP PUBLIC SCHOOL, NH-58 MEERUT ROAD, GHAZIABAD-201003(UP)

Ref. No- PST/ 2021-22

DATE- 17/07/2021

Dr. Brijesh Saran, Assistant Professor Psychiatry Santosh Medical College and Hospital Santosh Deemed to be University Ghaziabad, U.P.

Dear Dr. Brijesh Saran,

We are pleased to inform you that your application regarding approval of funding grant for the Research project titled "Evaluation of stigma in patients with Schizophrenia" for 12 months has been considered for funding grants by our Expert Committee after review.

The above said project is hereby approved by the Competent Authority and sanctioned total amount of Rs.9,000/- (Nine Thousand only).

Thank you and regards

For Purnima Scientific Traders

For Purnima Scientific Traders

AD Roy

Date: 12/05/2021

To,

Dr. Jyoti Batra

Dean Research

Santosh Deemed to be University

Subject: Request for research funding

Respected Mam,

We have received a request from your side for a research grant to conduct medical/dental research in various departments. We have received your proposals and revert back after review committee's decision.

S.No	Name of the Project, Clinical Trial, Endowment,Chairs	Name of the Principal Investigator/Co Investigator	
1	Identification of characteristics of TB inpatients with diabetes mellitus and COPD	Dr Sanjay Sahai	
2	A study to assess the practices related to Bio-Medical Waste Management among healthcare workers in a tertiary care centre	Dr Ritu Jain, DrRinku Garg	
3	A Comparative Evaluation of Stress Distribution and Deformation in Prosthetic Screw in Different Implant Configuration as Evaluated by FEM	Dr Priyanka Thukral	
4	An interventional study to evaluate the role of dietary supplementation of omega-3 fatty acids in dry eye syndrome	Dr Pratibha Gupta	
5	A cross-sectional study to evaluate the genomic diversity of rotavirus strainin children with diarrhoea visiting the tertiary care hospital	Dr Vishrut Singh	
6	A study to assess the spectrum of lesions of upperGIT through endoscopic biopsies and determine incidence of H. pylori among gastric lesions	Dr Malay Bajpai	
7	A cross-sectional study to find out the prevalence and associated factors of exclusive breastfeeding in urban areas of Ghaziabad, Uttar Pradesh	Ms Namrata Soni	

8	Assessment of mental wellbeing of school going adolescents using GHQ-12 questionnaire	Dr Amoolya Seth
9	A cross-sectional study to evaluate the predictive ability of mid-upper arm circumference (MUAC) for detecting severe wasting (weight-for-height Z-score (WHZ) <-3) among children aged 6-59 months.	Mr Pradhumn Katara
10	A case control study to analyse the association between UA and markers of oxidative stress and inflammation in diabetic nephropathy.	Dr Jyoti Batra
11	A prospective study to compare Acceptability, Safety and Continuation rateof Copper T 380A during immediate post placental insertion vs. Insertion within 48 hours of delivery	Dr Manisha Gupta
12	Bone turn over markers in diabetics and non diabetics	Dr Juhi Aggarwal, Dr Jyoti Batra
13	A study of an association between obesity in children and hypertension in adults	Dr Ritesh Kamal
14	A prospective study to compare ultrasonographic findings with clinical and radiographic findings in osteoarthritis (OA)-Affected knee joints	DrRakesh Gujjar
15	An observation of the bacteriological profile and antimicrobial susceptibility pattern of uropathogens with special reference to (Extended Spectrum beta Lactamase) ESBL producing strains.	Dr Shalabh Gupta

Himanshu Shukla (Authorized Signatory)

Date: 14/12/2021

To,

Dr. Jyoti Batra

Dean Research

Santosh Deemed to be University

Subject: Approval for research Funding

Respected Mam,

I am pleased to inform you I am ready to provide you a grant of INR 10,70,000 towards following projects by your faculty.

S.No	Name of the Project, Clinical Trial, Endowment, Chairs	Name of the Principal Investigator/Co Investigator	Department of Principal Investigator/ Co Investigator	Funds provided (INR in Lakhs)	Durationof the project
1	Identification of characteristics of TB inpatients with diabetes mellitus and COPD	Dr Sanjay Sahai	Faculty of Medicine	4.50	18 months
2	A study to assess the practices related to Bio-Medical Waste Management among healthcare workers in a tertiary care centre	Dr Ritu Jain, Dr Rinku Grag	Faculty of Medicine	0.30	24 months
3	A Comparative Evaluation of Stress Distribution and Deformation in Prosthetic Screw in Different Implant Configuration as Evaluated by FEM	Dr Priyanka Thukral	Faculty of Dentistry	1.50	12 months
4	An interventional study to evaluate the role of dietary supplementation of omega-3 fatty acids in dry eye syndrome	Dr Pratibha Gupta	Faculty of Medicine	0.20	6 months

5	A cross-sectional study to evaluate the genomic diversity of rotavirus strainin children with diarrhoea visiting the tertiary care hospital	Dr Vishrut Singh	Faculty of Medicine	0.15	6 months
6	A study to assess the spectrum of lesions of upperGIT through endoscopic biopsies and determine incidence of H. pylori among gastric lesions	Dr Malay Bajpai	Faculty of Medicine	0.15	6 months
7	A cross-sectional study to find out the prevalence andassociated factors of exclusive breastfeeding in urban areas of Ghaziabad, Uttar Pradesh	Ms Namrata Soni	Faculty of Medicine	0.30	6 months
8	Assessment of mental wellbeing of school going adolescents using GHQ-12 questionnaire	Dr Amoolya Seth	Faculty of Medicine	0.90	12 months
9	A cross-sectional study to evaluate the predictive ability of mid-upper arm circumference (MUAC) for detecting severe wasting (weight-for-height Z-score (WHZ) <-3) among children aged 6-59 months.	Mr Pradhumn Katara	Faculty of Medicine	0.40	6 months
10	A case control study to analyse the association between UA and markers ofoxidative stress and inflammation in diabetic nephropathy.	Dr Jyoti Batra	Faculty of Medicine	0.60	6 months
11	A prospective study to compare Acceptability, Safety and Continuation rateof Copper T 380A during immediate post placental insertion vs. Insertion within 48 hours of delivery	Dr Manisha Gupta	Faculty of Medicine	0.70	6 months

12	Bone turn over markers in diabetics and non diabetics	Dr Juhi Aggarwal, Dr Jyoti Batra	Faculty of Medicine	0.20	6 months
13	A study of an association between obesity in children and hypertension in adults	Dr Ritesh Kamal	Faculty of Medicine	0.30	6 months
14	A prospective study to compare ultrasonographic	DrRakesh Gujjar	Faculty of Medicine	0.20	6 months
15	An observation of the bacteriological profile and antimicrobial susceptibility pattern of uropathogens with special reference to (Extended Spectrum beta Lactamase) ESBL producing strains.	Dr Shalabh Gupta	Faculty of Medicine	0.30	6 months

Please share with me the full proposals within 30 days of receiving this letter. Further, please submit a copy of final project report post completion as well as the outcome/impact of the project.

Thank you and regards.

#### CC to:

- 1. Dr Sanjay Sahai
- 2. Dr Ritu Jain, Dr Rinku Grag
- 3. Dr Priyanka Thukral
- 4. Dr Pratibha Gupta
- 5. Dr Vishrut Singh
- 6. Dr Malay Bajpai
- 7. Ms Namrata Soni
- 8. Dr Amoolya Seth
- 9. Mr Pradhumn Katara
- 10.Dr Jyoti Batra
- 11.Dr Manisha Gupta
- 12.Dr Juhi Aggarwal, Dr Jyoti Batra
- 13.Dr Ritesh Kamal
- 14.Dr Rakesh Gujjar
- 15.Dr Shalabh Gupta

Himanshu Shukla
(Authorized Signatory)









# Nirmal Integrated Consultancy

A Private Limited Company with Registered Office at New Delhi Corporate Office at Gurugram (Haryana)

Information Centres: Yamuna Expressway, Greater Noida (U.P.),
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Overseas Offices: Australia, Nigeria, Tanzania, United States
CIN: U74999DL2021PTC391752 | TAN: DELN23929D

PAN:AAHCN9977B | GSTIN:06AAHCN9977B1Z4
www.team-nic.com | contact@team-nic.com

Dated: 01-Jul-2022

To,

Dr. Jyoti Batra, Dean Research Santosh Deemed to be University Ghaziabad, U.P., India

#### Sub.: Approval of Grant/cost for Research Support

#### Respected Sir/Madam,

This is in continuation to our past discussions and communications that Nirmal Integrated Consultancy Private Limited (Team-NIC) is pleased to approve a grant/cost of a total amount of 5,00,000 (INR Five Lakh Only) for support of below mentioned research projects at your University.

**List of Approved Projects:** 

#	Title of Project	Principal Investigator	Co-Investigator(s)	Amount (In Lakhs)
1.	Oral Health related quality of life among geriatric population in old age home in Ghaziabad City	Dr Kush Kalra	Dr. Mohit Dadu	1.35
2.	Evaluation of hematological profile in Oral Sub mucous fibrosis	Dr. Chandni Batra	Dr. Kanika Bhalla	0.55
3.	Effectiveness of International System for Reporting Serious Fluid Cystology in Routine Practice	Dr. Swati Singh	Dr. Mayurika Tyagi	1.75
4.	"Various Medications Used for Gastritis among Post-operative Patients in Surgery IPD in a Tertiary Care Hospital.",	Dr. Shaktibala Dutta	Dr. Jyotsna Sharma	1.35

#### Terms of Grant/cost:

- The grant/cost has been approved for consumption and deliveries within 12 month of release of this letter.
- The utilization details, progress reports, and the interim/final results of the investigations are required to be submitted to undersigned periodically for their reviews and comments.
- The respective departments of the University set free to choose the research team with the mentioned Principal Investigator/Co-Investigator(s). The respective team is expected to submit the expected project plan to Team-NIC within 30-days of release of this letter.
- Team-NIC reserves the right of using the outcomes of the research without further permissions/consents/intimations to/from the researcher(s) and at the same time it sets free the researcher and their affiliating organizations for the same.
- The research team is expected to share the complete and unbiased outcomes of the research within the timeline of the projects.
- 50% of the approved grant/cost would be released to the institution within 90-days of release of this letter
  whereas the balance would be released after receiving the satisfactory outcomes of the research or as to be
  mutually agreed.
- Team-NIC is free to cancel the balance grant/cost anytime without any obligation of clarifications to the
  research team/organization and at the same time there is no obligation on the research team/organization
  about refund of the released grant/cost for any reasons.

Kindly feel free to connect to undersigned for any further clarifications or support.

Best regards,

D. Jain

nef Advisor

0107 2022

20

Transforming Consultancy Globally Since 2001



## Re: Santosh Medical- Customer **Preference Study**



Hi Dr. Shweta, Kindly share your c...

View message





Amitav Ash to Me & 2 more Yesterday, 9:29 AM



Hi Shweta, please find details of Rs 25,000 paid towards incidental expenses. The toothpaste samples have also been dispatched to the address provided.

LP NDHN3TRF0IRN	SANTOSH 23575XK00JTR /6816402724 HSBCN21002726461	NONREF	TRANSFER	25,000.00
	2021/01/02 180728			

Warm regards

Amitav Ash

Disclaimer: This email message may contain confidential, proprietary or legally privileged information. Anyone who is not intended recipient should not use it. If you have erroneously received this message, please delete it immediately and notify the sender. The recipient acknowledges that Clove Dental is unable to exercise control to ensure or guarantee the integrity of / over the contents of the information contained in the email transmission and that any views expressed in this message are those of the individual sender and no binding nature of the message shall be implied or assumed unless the sender does so expressly with due authority of Clove Dental.

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#### SANTOSH TRUST

No.1 Santosh Nagar, Ghaziabad NCR - Delhi

E-Mail: accounts@santosh.ac.in

#### Receipt Voucher

No. : 7

Dated : 2-Jan-2021

Particulars	Amount
Account :	F-1
Miscelanious Receipts	25,000.00

Through:

INDIAN BANK - 6816402724

On Account of:

Being Sponsorship - Reasearch Amount Received from Star Dental C/AC FEES STAR DENTAL CENT HSBCN21002726461 TRANSFER FROM 97162000120 ( SDU - Indian - Rs.25000/- on 02.01.2021)

Bank Transaction Details:

NEFT

2-Jan-2021

25,000.00

Amount (in words):

**INR Twenty Five Thousand Only** 

₹ 25,000,00

Authorised Signatory

#### Tax Invoice

#### Dated Invoice No. TODAYS HEALTHCARE INDIA PRIVATE LIMITED 20-21/TP/00071 2-Jan-2021 F 29/6, Ist Floor, Okhla Industrial Area, Phase-2, New Delhi 110029 **Delivery Note** Mode/Terms of Payment GST:07AADCT1211A1Z7 Delhi - 110020, India Supplier's Ref. Other Reference(s) State Name: Delhi, Code: 07 E-Mail: tax@clovedental.in Dated Buyer's Order No. Buyer Star Dental Centre Pvt Ltd-Warehouse-Delhi **Delivery Note Date** Despatch Document No. F 29/6, Ist Floor, Okhla Industrial Area, Phase-II, New Delhi-110020 Despatched through Destination Delhi-110020 GSTIN/UIN : 07AAPCS5927C1Z5 Terms of Delivery State Name : Delhi, Code: 07 SI Description of Goods HSN/SAC Quantity Rate per Amount No. **Toothpaste Power 40G** 3306 1,008 Unit Unit 14,636.16 14.52 **Toothpaste Sensitive 40G** 3306 1,008 Unit 15.12 Unit 15,240.96 2 29,877.12 **CGST Payable** % 2,688.94 9 SGST Payable 9 % 2,688.94 2,016 Unit Total 35,255.00 Amount Chargeable (in words) E. & O.E INR Thirty Five Thousand Two Hundred Fifty Five Only Taxable Central Tax State Tax Total Value Rate Amount Rate Amount Tax Amount 29,877.12 9% 2,688.94 9% 2,688.94 5,377.88 29,877.12 2,688.94 5,377.88 Total: 2,688.94 Tax Amount (in words): INR Five Thousand Three Hundred Seventy Seven and Eighty Eight paise Only for TODAYS HEALTHCARE INDIA PRIVATE LIMITED We declare that this invoice shows the actual price of the goods described and that all particulars are true

SUBJECT TO SUBJECT TO DELHI JURISDICTION JURISDICTION

This is a Computer Generated Invoice

**Authorised Signatory** 

### **DHANVANTRA HEALTH CARE PRIVATE LIMITED**

Registered office & Corporate office: NH 45 Trichy Chennai Trunk Road, Near Samayapuram Toll Plaza,
Samayapuram Post, Tiruchirappalli - 621 112, Fax: +91 431 2675353

Date: 20th January, 2022

Dr Jyoti Batra (Dean Research)

Santosh Deemed to be University

Ghaziabad, U.P., India

To,

Sub.: Grant for Research Support

Respected Sir/Madam,

This is to inform you that after thorough review of your research proposals submitted, we are pleased to approve a grant/donation of a total amount of 12,80,000 (INR) for support of your below mentioned research projects:

S.No	Title	Name of Principal Investigator	Amount Sanctioned (INR)
1	Mucin 4 expression in Oral Leukoplakia : An immunohistochemical study	Dr Kanika Bhalla Prabhat	0.85
2	An evaluation of changes in anxiety and behavior profile of children treated under inhalation sedation using nitrous oxide over 2-6 sequential follow up treatment visits	Dr Neeti Mittal	0.80
3	A randomized clinical trial to compare the clinical performance of indirect composite onlays and preformed zirconia crown for full coverage restoration of primary molars post-pulpectomy	Dr Shweta Bali	1.95
4	Prevalence of TMJ disorders in the local population of Ghaziabad City	Dr Chandni Batra, Dr Kanika Bhalla, Dr Priyanka Bhushan	1.35
5	Effect of premedication with three oral analgesics on the success of inferior alveolar nerve block in patients with symptomatic irreversible pulpitis - randomize control trial	Dr Chetna Arora	0.49
6	Oral Health related quality of life among School going Children in District Ghaziabad	Dr Mohit Dadu	0.09
7	To detect and assess DNA damage by Comet Assay from buccal epithelial cells of Smokeless tobacco users and non user.	Dr Shreya Singh	2.12
8	Prevalence of non-alcoholic fatty liver diseases in children	Dr Veenu Aggarwal	1.20
9	Efficacy of aminophylline versus caffine for preventing apnea of prematurity	Dr Alka Aggarwal	1.10
10	Acute renal failure in full term neonates with perinatal asphyxia	Dr Veenu Aggarwal	1.85
11	Aging and Levels of Leptin in Our Body	Dr Jyoti Batra	1.00

#### **Terms of Grant:**

- The utilization details and the final results of the investigations are required to be submitted to undersigned at project completion for their reviews and comments.
- The respective departments of the University are free to choose the research team with the mentioned Principal Investigator/Co-Investigator(s).

Kindly feel free to connect to undersigned for any further clarifications or support.

Best regards
Authorized Signatory

Embee Diagnostics Put. Ltd.

GSTIN: 07AAACE0709K1ZV

SILVER JUBILEE YEAR 2010 Date: 01/03/2022

Ref. No. EDPL/SH/21-22

To.

Dr. Geeta Gupta , Dr.Dakshina Bisht, Dr.Ritu Jain &Dr.Ashutosh Rawat Department of Microbiology Santosh Medical College and Hospital Santosh Deemed to be University Ghaziabad, U.P.

Dear Doctor,

We are pleased to inform you that following a thorough examination of your project titled as below:

Title	Department	Principal Investigator	Amount
Surveilliance of drug resistant gram negative bacteria in tertiary care hospital	Microbiology	Dr. Geeta Gupta	50,000/-
Virulence factors in candida speciesfrom various clinical samples	Microbiology	Dr.Dakshina Bisht	50,000/-
Fungal infection in CSOM	Microbiology	Dr.Ritu Jain	25,000/-
Prevalence of candidiasis in school going children	Microbiology	Dr.AshutoshTawat	25,000/-
			1.50.000/

Against the above projects, consumables worth Rs.150,000.00 (Rs. One Lakh Fifty Thousand Only ) have been supplied to the Hospital /College.

Please send us a detailed report of your results after the assignment is complete.

Best Regards, and thank you for your time and attention

Copy to-

- 1) Academic section
- 2) Dean Research office

From Embee Diagnostics Pvt.Ltd

Director

ONO PIO TENDE

Regd. Off.: 1864/65,Havell Jugal Kishore, Chandni Chowk, Delhi-11006 Ph.: 47186465, 40113277, 23267172, 23283236
Website: www.embeedlagnostics.com E-mail: mohak@embeedlagnostics.com
CIN: U74899DL1984PTC018547 PAN: AAACE0709K GSTIN: 07AAACE0709K1ZV

Date: 20/08/2021

To,

Dr. Jyoti Batra

Dean Research

Santosh Deemed to be University

Subject: Request for research funding

#### Respected Mam,

We have received a request from your side for a research grant to conduct medical/dental research in various departments. We have received your proposals and revert back after review committee's decision.

S.No	Name of the Project, Clinical Trial, Endowment, Chairs	Name of the Principal Investigator/Co Investigator	
1	Pattern of caries in adolescents	Dr. Mohit Dadu	
2	A Comparative Assessment of the Upper Pharyngeal Airway Dimensions in different facial types : a cephalometric study	Dr Tina Chugh	
3	A randomized controlled trial to comparatively evaluate the effect of Silver diamine fluoride and Fluoride varnish on preventing new carious lesions in children with high caries risk	Dr Nidhi Gupta	
4	To compare and evaluate the primary and secondary implant stability between calcium phosphate surface coated implants and alumina blasted/acid etched implants using resonance frequency analysis.	Dr Shweta Bali	

eraj Mehrg Dheeraj Mehra (Authorized Signatory)

Date: 04/02/2022

To,

Dr. Jyoti Batra

Dean Research

Santosh Deemed to be University

Subject: Approval for research funding

Respected Mam,

I am pleased to inform you I am ready to provide you a grant of INR 4,00,000 towards following projects by your faculty

S.No	Name of the Project	Name of the Principal Investigator/Co Investigator	Funds provided (INR in Lakhs)	Duration of the project
1	Pattern of caries in adolescents	Dr. Mohit Dadu	0.40	6 months
2	A Comparative Assessment of the Upper Pharyngeal Airway Dimensions in different facial types: a cephalometric study	Dr Tina Chugh	0.80	12 Months
3	A randomized controlled trial to comparatively evaluate the effect of Silver diamine fluoride and Fluoride varnish on preventing new carious lesions in children with high caries risk	Dr Nidhi Gupta	1.25	9 months
4	To compare and evaluate the primary and secondary implant stability between calcium phosphate surface coated implants and alumina blasted/acid etched implants using resonance frequency analysis.	Dr Shweta Bali	1.55	6 months

Please share with me the full proposals within 30 days of receiving this letter. Further, please submit a copy of final project report post completion as well as the outcome/impact of the project.

Thank you and regards.

Dheeraj Hehra
(Authorized Signatory)

CC to:

- 1. Dr. Mohit Dadu
- 2. Dr Tina Chugh
- 3. Dr Nidhi Gupta
- 4. Dr Shweta Bali

Date: 11/06/2021

To,

Dr. Jyoti Batra

Dean Research

Santosh Deemed to be University

Subject: Request for research funding

Respected Mam,

We have received a request from your side for a research grant to conduct medical/dental research in various departments. We have received your proposals and revert back after review committee's decision.

S.No	Name of the Project, Clinical Trial,	Name of the Principal	
	Endowment, Chairs	Investigator/Co Investigator	
1	To evaluate and compare the disinfection achieved in canals by single file system (Hyflex EDM-B) using two different irrigants in removal of smear layer.	Dr Shubhra Malik Juneja	
2	A comparative evaluation of the efficacy of electrocautery versus radiofrequency cautery for incisions in surgical removal of mandibular third molar.	Dr Amit B Lall	

28121

То,

21.01.2022

Dr Jyoti Batra

Dean Research

Santosh Deemed to be University

Subject: Approval for research funding

## Respected Mam,

I am pleased to inform you after thorough discussion with you and your faculty members, I am ready to fund the following research projects worth a sum of INR 5,00,000.

Dated:

S.No.	Title	Name of Principal investigator	Amount (INRin Lakhs)	Study duration
1	To evaluate and compare the disinfection achieved in canals by single file system (Hyflex EDM-B) using two different irrigants in	Dr Shubhra Malik Juneja	2.10	24 months

Page 169 of 335

	removal of smear layer.			
2	A comparative evaluation of the efficacy of electrocautery versus radiofrequency cautery for incisions in surgical removal of mandibular third molar.	Dr Amit B Lall	2.90	24 months

Please share with me the full proposals within 30 days of receiving this letter. Further, please submit a copy of final project report post completion.

Thank you and regards

CC to.

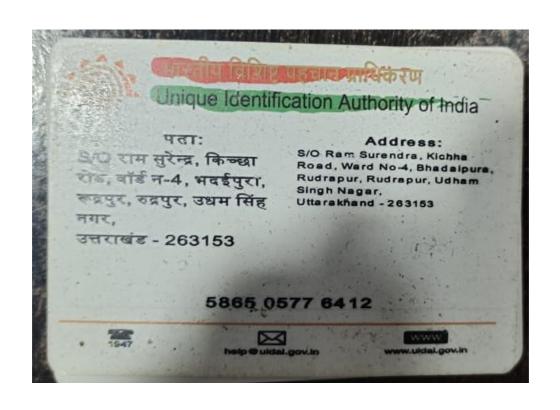
- 1. Dr Shubhra Malik Juneja
- 2. Dr Amit B Lall

Mr Harish Yadav (Authorized Signatory)



Page 171 of 335





Date: 08/07/2021

To,

Dr. Jyoti Batra

Dean Research

Santosh Deemed to be University

Subject: Request for research funding

#### Respected Mam,

We have received a request from your side for a research grant to conduct medical/dental research in various departments. We have received your proposals and revert back after review committee's decision.

SNo	Title	Name of the Principal Investigator/Co Investigator	
1.	Socket preservation with beta-tricalcium phosphate: a Clinico-radiographic evaluation	Dr Sanjeev Tomar	
2.	Evaluation of hematological profile in Oral Sub mucous fibrosis	Dr Chandni Batra	
3.	Morphometric and Radiological Analysis of The Size of the Foot and It's Correlation with Stature in Different Age Groups of Indian Population	Dr. Nisha Kaul	
4.	Evaluation of examination stress on memory and EEG in male and Female medical students	Dr. Rinku Garg	
5.	Effect of yoga on mental health of first year students	Dr. Navpreet Mann	

Radha Yadav

Rodhayadak

(Authorized Signatory)

Date: 30/01/2022

To,

Dr. Jyoti Batra

Dean Research

Santosh Deemed to be University

Subject: Approval for research funding

Respected Mam,

I am pleased to inform you after thorough discussion with you and your faculty members, I am ready to fund the following research projects worth a sum of INR 5,00,000.

SNo	Title	Name of the Principal Investigator/Co Investigator	Funds Provided (INR in Lakhs)	Duration of the Project
1.	Socket preservation with beta- tricalcium phosphate: a Clinico- radiographic evaluation	Dr Sanjeev Tomar	1.32	12 Months
2.	Evaluation of hematological profile in Oral Sub mucous fibrosis	Dr Chandni Batra	0.68	6 Months
3.	Morphometric and Radiological Analysis of The Size of the Foot and Its Correlation with Stature in Different Age Groups of Indian Population	Dr. Nisha Kaul	1.00	12 Months
4.	Evaluation of examination stress on memory and EEG in male and Female medical students	Dr. Rinku Garg	1.00	12 Months
5.	Effect of yoga on mental health of first year students	Dr. Navpreet Mann	1.00	12 Months

Please share with me the full proposals within 30 days of receiving this letter. Further, please submit a copy of final project report post completion.

Thank you and regards.

Radha Yadav (Authorized Signatory)

#### CC to:

- 1. Dr Sanjeev Tomar
- 2. Dr Chandni Batra
- 3. Dr Nisha Kaul
- 4. Dr Rinku Garg
- 5. Dr Navpreet Mann





Date: 11/06/2021

To,

Dr. Jyoti Batra

Dean Research

Santosh Deemed to be University

Subject: Request for research funding

Respected Mam,

We have received a request from your side for a research grant to conduct medical/dental research in various departments. We have received your proposals and revert back after review committee's decision.

S.No	Name of the Project, Clinical Trial, Endowment, Chairs	Name of the Principal Investigator/Co Investigator
1	Findings in prostate cancer patients by Magnetic resonance	Dr Ashish Kumar Shukla
	spectroscopy (MRS)	

Anupama Khanna (Authorized Signatory)

Alshanna

Date: 25/01/2022

To,

Dr. Jyoti Batra

Dean Research

Santosh Deemed to be University

Subject: Approval for research funding

Respected Mam,

I am pleased to inform you after thorough discussion with you and your faculty members, I am ready to fund the following research projects worth a sum of INR 1,15,000.

S.No.	Title	Name of	Amount	Study
		Principal	(INR in	duration
		investigator	Lakhs)	
1.	Findings in prostate cancer patients by Magnetic resonance spectroscopy (MRS)	Dr Ashish Kumar Shukla	1.15	24 months

Please share with me the full proposals within 30 days of receiving this letter. Further, please submit a copy of final project report post completion.

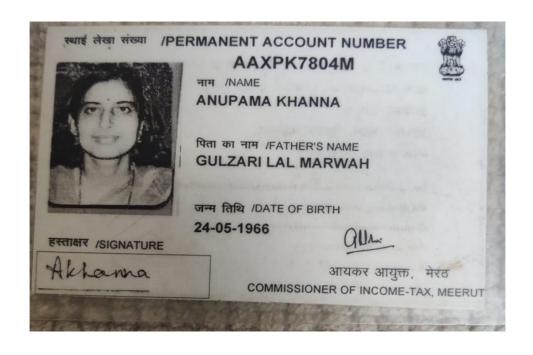
Thank you and regards.

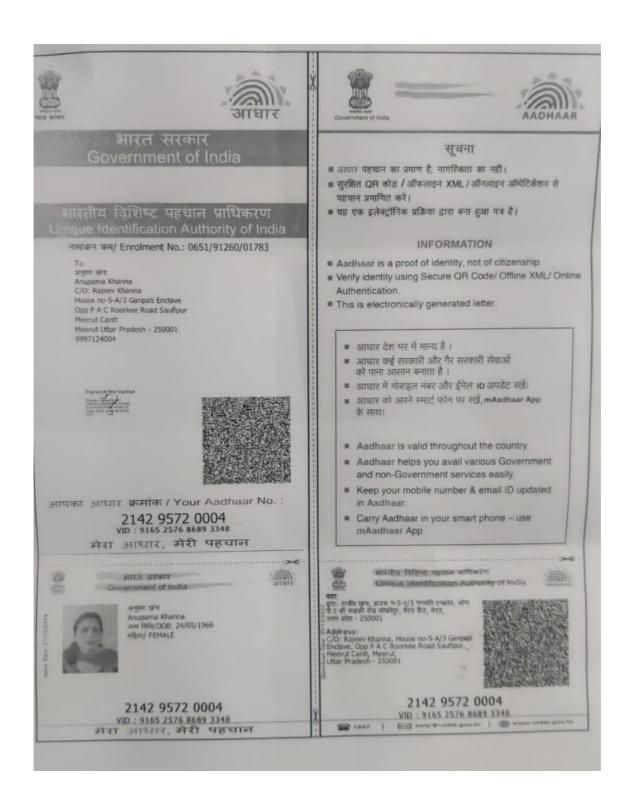
CC to:

1. Dr Ashish Kumar Shukla

Anupama Khanna (Authorized Signatory)

Alshanna





Date: 08/07/2021

To,

Dr. Jyoti Batra

Dean Research

Santosh Deemed to be University

Subject: Request for research funding

Respected Mam,

We have received a request from your side for a research grant to conduct medical/dental research in various departments. We have received your proposals and revert back after review committee's decision.

S.No.	Title	Name of Principal investigator
1.	Comparative study between conventional adenoidectectomy and powered instrument adenoidectomy	Dr Vandana Singh

Mani Khanna

(Authorized Signatory)

To,

Dr. Jyoti Batra

Dean Research

Santosh Deemed to be University

Subject: Approval for research funding

Respected Mam,

I am pleased to inform you after thorough discussion with you and your faculty members, I am ready to fund the following research projects worth a sum of INR 1,50,000.

S.No.	Title	Name of Principal investigator	Amount (INR in Lakhs)	Study duration
1.	Comparative study between conventional adenoidectectomy and powered instrument adenoidectomy	Dr Vandana Singh	1.50	24 Months

Please share with me the full proposals within 30 days of receiving this letter. Further, please submit a copy of final project report post completion.

Thank you and regards.

Mani Khanna

(Authorized Signatory)

CC to:

1. Dr Vandana Singh





#### भारत सरकार Government of India

#### भारतीय विशिष्ट पहचान प्राधिकरण Unique Identification Authority of India

नामांकन जम/ Enrolment No.: 0000/00652/20445

To मणि खंगा Mani Khanna Wife of Albillesh Khanna C011 Harmony Yower The Peaceful Homes Near Tulip Chownk Sec 70 A Paira(164) Gurgaon Haryana - 122101 9720210191





आपका आधार क्रमांक / Your Aadhaar No. :

8457 7311 3469

मेरा आधार, मेरी पहचान

भारत सरकार





8457 7311 3469 VID: 9182 1974 7511 3907

मेरा आधार, मेरी पहचान



#### सूचना

- जाधार प्रध्यान का प्रमाण है, नागरिकता का नहीं।
- सुरक्तित QR कोड / ऑफलाइन XML / ऑनलाइन ऑबेटिकेशन से पहचान प्रमाणित करें।
- यह एक इलेक्ट्रॉनिक प्रक्रिया द्वारा बना हुआ पत्र है।

#### INFORMATION

- Aadhaar is a proof of identity, not of citizenship.
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  - आधार देश घर में मान्य है ।
  - आधार कई सरकारी और गैर सरकारी सेवाओं को पाना आसान बनाता है।
  - आधार में मोबाइल नंबर और ईमेल ID अपडेट रखें।
  - आधार को अपने स्मार्ट फोन पर रखें, mAadhaar App के साधा
  - Andhaar is valid throughout the country.
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भारतीय विशिष्ट पहचान प्राधिकरण Unique Identification Authority of India



च्याः पद्माः औम् अस्तिगेत कन्या, संवश्य हरमसी टावर से पीक्यान होन्या, निमद दुनिय चीक, सेक्स धक ा, प्रकार १६४), गुजर्गीत, सरमाणा - 172101

Address: Wife of Akhilesh Khanna, C011 Harmony Tower The Peaceth Homes, Near Tulto Chrownk, Sec 70 A, Palra (164), Gurgeon, Haryena - 122101



8457 7311 3469

VID: 9182 1974 7511 3907

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# भारत सरकार GOVT. OF INDIA

#### ई- स्थायी लेखा संख्या कार्ड e - Permanent Account Number (e-PAN) Card AYZPG3134E

TIII / Name MANI KHANNA

DEVENDRA KUMAR GARG

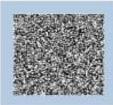
बना की लाडिब / Date of Birth 21/08/1991

film / Gender Female



विता का नाम / Father's name

remar / Signature





- Permanent Account Number (PAN) facilitate Income Tax Department linking of various documents, including payment of taxes, assessment, tax demand tax arears, matching of information and easy maintenance & restleval of electronic information etc. relating to a taxpuyer, कथा लेखा कांच्या (भिन) एक कराया से संबंधित क्षित्र एकानीओं के पेदेन में अक्का विभाग को महावक होता है, जिसमें को के पुण्यान, आकरन, कर मांग, टेक्स बकाय, सुक्त के जिला और इस्कृतिक आजवार का आधार प्रकृतिक के बात के प्राथम के प्रकृति अपन्यान के साथ प्रकृतिक के बात के प्रवाद के प्रकृति के प्रवाद के
- Quoting of PAN is now mandatury for several transactions specified under income Tax Act, 1961 (Refer Rule 1148 of Income Tax Rules, 1962) आधार अधिनिया, 1961 के तक निष्टि वर्ज लेन्द्रेन के लिए स्थापी लेखा लावा (पैन) का आँख अब अनिवार्ज हैं। (अधावत नियम, 1962 के निवस 1148, का संदर्भ तो)
- Possessing or using more than one PAN is against the law & may atment penalty of upto Bs. 10,000, the it offers until character (\$\frac{1}{2}\$) we can its ready were \$\frac{1}{2}\$ and \$\frac{1}{2}
- The PAN Card enclosed contains Enhanced QR Code which is readable by a specific Android Mobile App. Keyword to search this specific Mobile App on Google Play Store is "Enhanced QR Code Reset for PAN Card. संस्था पैन सबसे में एकाला अपूत्राम करेड मामिल है जो एक लिकिट पहुँचेंड सोमाइल ऐप हुए। इन्हेंब है। Google Play Store पर इस निविध मोमाइल ऐप को खोजने के लिए बीचाई "Enhanced QR Code Reader for PAN Card" है।



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Electronically laused and Digitally signed ePAM is a valid mode of liseur of Permanent Acrosset Number (PAM) past amendments in classe (c) is the Explanation occurring other sub-section (6) of Section 139A of Income Tax Act, 1961 and sub-rule (6) of Rule 114 of the Income Tax Rules,

Date: 24/07/2021

To,

Dr. Jyoti Batra

Dean Research

Santosh Deemed to be University

Subject: Request for research funding

Respected Mam,

We have received a request from your side for a research grant to conduct medical/dental research in various departments. We have received your proposals and revert back after review committee's decision.

SNo.	Title of the Project	Name of the Principal Investigator
1	Evaluation of role of high densityporous polyethylene implants in correction of chin deformities	Dr Mayank Singhal
2	Pattern of suicide in Femaleswith mental disorders	Dr. Shilpa singh
3	To evaluate and compare the Apical transportation and canal centering ability in the Mesio- buccal root of maxillary first molar using three different rotary file systems(Protaper gold, Hyflex EDMand Trunatomy)	Dr Sumita Giri
4	Reduction in incidence of postoperative sore throat after endotracheal intubation in middle ear surgeries by preoperativegargaling with ketamine	Dr Anil Kumar
5	Evaluation of early Menopause symptoms in Post- Hysterectomyand Premature Ovarian insufficiency in women ofreproductive age group	Dr Alpana Aggarwal
6	A randomized clinical trial to comparatively evaluate the clinicalefficacy of LMA Supreme™, and Ambu AuraGain™ in adult patientsduring general anesthesia	Dr Debpriya Sarkar

ल मुन्द्र

Mr Dharmendra Yadav (Authorized Signatory)

Date: 21/01/2022

To,

Dr. Jyoti Batra

Dean Research

Santosh Deemed to be University

Subject: Approval for research funding

Respected Mam,

I am pleased to inform you after thorough discussion with you and your faculty members, I am ready to fund the following research projects worth a sum of INR 5,00,000.

Title of the Project	Name of the Principal Investigator	Funds provided (INR in Lakhs)	Duration of the project
Evaluation of role of high density porous polyethylene implants in correction of chin deformities	Dr Mayank Singhal	1.27	9 months
Pattern of suicide in Females with mental disorders	Dr. Shilpa singh	1.6	24 Months
To evaluate and compare the Apical transportation and canal centering ability in the Mesiobuccal root of maxillary first molar using three different rotary file systems(Protaper gold,Hyflex EDM and Trunatomy)	Dr Sumita Giri	1.13	12 Months
Reduction in incidence of postoperative sore throat after endotracheal intubation in middle ear surgeries by preoperative gargaling with ketamine	Dr Anil Kumar	0.3	24 months
Evaluation of early Menopause symptoms in Post-Hysterectomy and Premature Ovarian insufficiency in women of reproductive age group	Dr Alpana Aggarwal	0.4	24 months
A randomized clinical trial to comparatively evaluate the clinical efficacy of LMA Supreme™, and Ambu AuraGain™ in adult patients during general anesthesia	Dr Debpriya Sarkar	0.3	24 months

Please share with me the full proposals within 30 days of receiving this letter. Further, please submit a copy of final project report post completion.

Thank you and regards.

Mr Dharmendra Yadav (Authorized Signatory)

#### CC to:

- 1. Dr Mayank Singhal
- 2. Dr Shilpa Singh
- 3. Dr Sumita Giri
- 4. Dr Anil Kumar
- 5. Dr Alpana Aggarwal
- 6. Dr Debpriya Sarkar







Date: 08/07/2021

To,

Dr. Jyoti Batra

Dean Research

Santosh Deemed to be University

Subject: Request for research funding

# Respected Mam,

We have received a request from your side for a research grant to conduct medical/dental research in various departments. We have received your proposals and revert back after review committee's decision.

SNo	Title Name of the Investigator/Co Investiga		
1.	Socket preservation with beta-tricalcium phosphate: a Clinico-radiographic evaluation	Dr Sanjeev Tomar	
2.	Evaluation of hematological profile in Oral Sub mucous fibrosis	Dr Chandni Batra	
3.	Morphometric and Radiological Analysis of The Size of the Foot and It's Correlation with Stature in Different Age Groups of Indian Population	Dr. Nisha Kaul	
4.	Evaluation of examination stress on memory and EEG in male and Female medical students	Dr. Rinku Garg	
5.	Effect of yoga on mental health of first year students  Dr. Navpreet Mann		

Radha Yadav

Rodhayadak

(Authorized Signatory)

To,

Dr. Jyoti Batra

Dean Research

Santosh Deemed to be University

Subject: Approval for research funding

Respected Mam,

I am pleased to inform you after thorough discussion with you and your faculty members, I am ready to fund the following research projects worth a sum of INR 5,00,000.

SNo	Title	Name of the Principal Investigator/Co Investigator	Funds Provided (INR in Lakhs)	Duration of the Project
1.	Socket preservation with beta- tricalcium phosphate: a Clinico- radiographic evaluation	Dr Sanjeev Tomar	1.32	12 Months
2.	Evaluation of hematological profile in Oral Sub mucous fibrosis	Dr Chandni Batra	0.68	6 Months
3.	Morphometric and Radiological Analysis of The Size of the Foot and Its Correlation with Stature in Different Age Groups of Indian Population	Dr. Nisha Kaul	1.00	12 Months
4.	Evaluation of examination stress on memory and EEG in male and Female medical students	Dr. Rinku Garg	1.00	12 Months
5.	Effect of yoga on mental health of first year students	Dr. Navpreet Mann	1.00	12 Months

Please share with me the full proposals within 30 days of receiving this letter. Further, please submit a copy of final project report post completion.

Thank you and regards.

Radha Yadav (Authorized Signatory)

#### CC to:

- 1. Dr Sanjeev Tomar
- 2. Dr Chandni Batra
- 3. Dr Nisha Kaul
- 4. Dr Rinku Garg
- 5. Dr Navpreet Mann





Date: 24/07/2021

To,

Dr. Jyoti Batra

Dean Research

Santosh Deemed to be University

Subject: Request for research funding

Respected Mam,

We have received a request from your side for a research grant to conduct medical/dental research in various departments. We have received your proposals and revert back after review committee's decision.

SNo.	Title of the Project	Name of the Principal Investigator
1	Evaluation of role of high densityporous polyethylene implants in correction of chin deformities	Dr Mayank Singhal
2	Pattern of suicide in Femaleswith mental disorders	Dr. Shilpa singh
3	To evaluate and compare the Apical transportation and canal centering ability in the Mesio- buccal root of maxillary first molar using three different rotary file systems(Protaper gold, Hyflex EDMand Trunatomy)	Dr Sumita Giri
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5	Evaluation of early Menopause symptoms in Post- Hysterectomyand Premature Ovarian insufficiency in women ofreproductive age group	Dr Alpana Aggarwal
6	A randomized clinical trial to comparatively evaluate the clinicalefficacy of LMA Supreme™, and Ambu AuraGain™ in adult patientsduring general anesthesia	Dr Debpriya Sarkar

लामुट्स

Mr Dharmendra Yadav (Authorized Signatory)

Date: 21/01/2022

To,

Dr. Jyoti Batra

Dean Research

Santosh Deemed to be University

Subject: Approval for research funding

Respected Mam,

I am pleased to inform you after thorough discussion with you and your faculty members, I am ready to fund the following research projects worth a sum of INR 5,00,000.

Title of the Project	Name of the Principal Investigator	Funds provided (INR in Lakhs)	Duration of the project
Evaluation of role of high density porous polyethylene implants in correction of chin deformities	Dr Mayank Singhal	1.27	9 months
Pattern of suicide in Females with mental disorders	Dr. Shilpa singh	1.6	24 Months
To evaluate and compare the Apical transportation and canal centering ability in the Mesiobuccal root of maxillary first molar using three different rotary file systems(Protaper gold,Hyflex EDM and Trunatomy)	Dr Sumita Giri	1.13	12 Months
Reduction in incidence of postoperative sore throat after endotracheal intubation in middle ear surgeries by preoperative gargaling with ketamine	Dr Anil Kumar	0.3	24 months
Evaluation of early Menopause symptoms in Post-Hysterectomy and Premature Ovarian insufficiency in women of reproductive age group	Dr Alpana Aggarwal	0.4	24 months
A randomized clinical trial to comparatively evaluate the clinical efficacy of LMA Supreme™, and Ambu AuraGain™ in adult patients during general anesthesia	Dr Debpriya Sarkar	0.3	24 months

Please share with me the full proposals within 30 days of receiving this letter. Further, please submit a copy of final project report post completion.

Thank you and regards.

Mr Dharmendra Yadav (Authorized Signatory)

#### CC to:

- 1. Dr Mayank Singhal
- 2. Dr Shilpa Singh
- 3. Dr Sumita Giri
- 4. Dr Anil Kumar
- 5. Dr Alpana Aggarwal
- 6. Dr Debpriya Sarkar







Date: 24/07/2021

To,

Dr. Jyoti Batra

Dean Research

Santosh Deemed to be University

Subject: Request for research funding

Respected Mam,

We have received a request from your side for a research grant to conduct medical/dental research in various departments. We have received your proposals and revert back after review committee's decision.

SNo	Title	Name of Principal investigator
1	Bacteriological Study of Conjunctivitis.	Dr Somesh Ranjan

**Akhilesh Khanna** 

(Authorized Signatory)

Alli but than

To,

Dr. Jyoti Batra

Dean Research

Santosh Deemed to be University

Subject: Approval for research funding

# Respected Mam,

I am pleased to inform you after thorough discussion with you and your faculty members, I am ready to fund the following research projects worth a sum of INR 1,50,000.

S.No.	Title	Name of Principal investigator	Amount (INR in Lakhs)	Study duration
1.	Bacteriological Study of Conjunctivitis.	Dr Somesh Ranjan	1,50,000/-	24 Months

Please share with me the full proposals within 30 days of receiving this letter. Further, please submit a copy of final project report post completion.

Thank you and regards.

**Akhilesh Khanna** 

Alli hut than

(Authorized Signatory)

#### CC to.

1. Dr Somesh Ranjan







#### भारत सरकार Government of India

# भारतीय विशिष्ट पहचान प्राधिकरण Unique Identification Authority of India

नामांकन कम/ Enrolment No.: 0000/00120/80273

To offside gree Athlesh Manna C 011 Harmony tower AIPL The peoceful homes Sec 70 A Palra(164) Gurgaon Haryana - 122101 9045850009





आपका आधार क्रमांक / Your Aadhaar No. :

2555 5247 7710 VID: 9101 8558 2378 0894

मेरा आधार, मेरी पहचान



2555 5247 7710 VID: 9101 8558 2378 0894



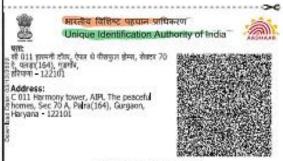


#### सूचना

- आधार पहचान का प्रमाण है, नागरिकता का नहीं।
- सुरक्षित QR कोड / ऑफलाइन XML/ ऑनलाइन ऑबेटिकेशन से पडचान प्रमाणित करें।
- यह एक इलेक्ट्रॉनिक प्रक्रिया द्वारा बना हुआ पत्र है।

#### INFORMATION

- Aadhaar is a proof of identity, not of citizenship.
- Verify identity using Secure QR Code/ Offline XML/ Online Authentication.
- This is electronically generated letter.
  - आधार देश भर में मान्य है ।
  - आधार कई सरकारी और गैर सरकारी सेवाओं को पाना आसान बनाता है।
  - आधार में मोबाइल नंबर और ईमेल ID अपडेट रखें।
  - आधार को अपने स्मार्ट फोन पर रखें, mAadhaar App के साथ।
  - Aadhaar is valid throughout the country.
  - Aadhaar helps you avail various Government and non-Government services easily.
  - Keep your mobile number & email ID updated in Aadhaar.
  - Carry Aadhaar in your smart phone use mAadhaar App.



2555 5247 7710 VID: 9101 8558 2378 0894

That I No beinduidal needs I off wee

Date: 26/08/2021

To,

Dr. Jyoti Batra

Dean Research

Santosh Deemed to be University

Subject: Request for research funding

Respected Mam,

We have received a request from your side for a research grant to conduct medical/dental research in various departments. We have received your proposals and revert back after review committee's decision.

S.No.	Title	Name of Principal investigator
1	Comparison of results of silastic intra nasal splint and merocel nasal pack in septoplasty	Dr Sushil Gaur
2	A Study on the Correlation BetweenType 2 Diabetes Mellitus and Osteoporosis with reference to Osteopontin Levels	Dr Jyoti Batra
3	Preferred Medications Used among neonates admitted to NICU in Santosh Medical College & Hospital, Santosh Deemed to be University, Ghaziabad.	Dr Jyotsna Sharma

Jitender Kumar

Date: 21/02/2022

To,

Dr. Jyoti Batra

Dean Research

Santosh Deemed to be University

Subject: Approval for research funding

# Respected Mam,

I am pleased to inform you after thorough discussion with you and your faculty members, I am ready to fund the following research projects worth a sum of INR 4,30,000.

S.No.	Title	Name of Principal investigator	Amount (INR in Lakhs)	Study duration
1	Comparison of results of silastic intra nasal splint and merocel nasal pack in septoplasty	Dr Sushil Gaur	1.60	24 Months
2	A Study on the Correlation Between Type 2 Diabetes Mellitus and Osteoporosis with reference toOsteopontin Levels	Dr Jyoti Batra	0.70	12 Months
3	Preferred Medications Used among neonates admitted to NICU in Santosh Medical College & Hospital, Santosh Deemed to be University, Ghaziabad.	Dr Jyotsna Sharma	2.00	24 Months

Please share with me the full proposals within 30 days of receiving this letter. Further, please submit a copy of final project report post completion.

Thank you and regards.

litendra Kumar

CC to:

- 1. Dr Sushil Gaur
- 2. Dr Jyoti Batra
- 3. Dr Jyotsna Sharma

Date: 24/07/2021

To,

Dr. Jyoti Batra

Dean Research

Santosh Deemed to be University

Subject: Request for research funding

Respected Mam,

We have received a request from your side for a research grant to conduct medical/dental research in various departments. We have received your proposals and revert back after review committee's decision.

SNo	Title	Name of Principal investigator
1	Role of Polysomnography in Detection of Overlap Syndrome in COPD Patients	Dr. Prachi Saxena

Anuj Ahuja

(Authorized Signatory)

To,

Dr. Jyoti Batra

Dean Research

Santosh Deemed to be University

Subject: Approval for research funding

#### Respected Mam,

I am pleased to inform you after thorough discussion with you and your faculty members, I am ready to fund the following research projects worth a sum of INR 2,50,000.

S.No.	Title	Name of Principal investigator	Amount (INR in Lakhs)	Study duration
1.	Role of Polysomnography in Detection of Overlap Syndrome in COPD Patients	Dr. Prachi Saxena	2.50	24 Months

Please share with me the full proposals within 30 days of receiving this letter. Further, please submit a copy of final project report post completion.

Thank you and regards.

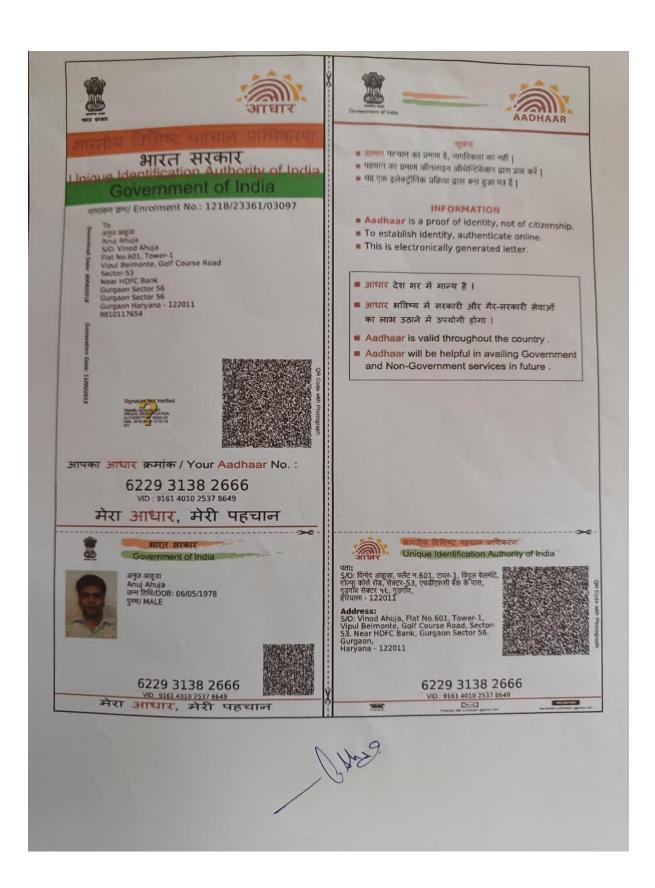
Anuj Ahuja

(Authorized Signatory)

CC to:

1. Prachi Saxena





Date: 11/06/2021

To,

Dr. Jyoti Batra

Dean Research

Santosh Deemed to be University

Subject: Request for research funding

Respected Mam,

We have received a request from your side for a research grant to conduct medical/dental research in various departments. We have received your proposals and revert back after review committee's decision.

S. No.	Title of the Project	Name of the PrincipalInvestigator
1	Evaluation of Cognitive Dysfunction in Recovered BipolarDisorder Patients Compared withBiological Marker	Dr Brijesh Saran
2	Diagnosis of Schizophrenic withBiological Marker and MRI	Dr Amoolya Seth
3	Study of Spectrum of Lesions inBone Marrow Aspiration and Terphine Biopsy from a TertiaryCare Center	Dr Prem Garg
4	Importance of Family Studies with High Performance LiquidChromotography (HPLC) in Hemoglobin Disorders	Dr Abhishek Pathre
5	Various Medications Used for Gastritis among Post-operativePatients in Surgery IPD in a Tertiary Care Hospital	Dr Vivek Tejvir Yadav

Chandra Shekhar Mittal (Authorized Signatory)

To,

Dr. Jyoti Batra

Dean Research

Santosh Deemed to be University

Subject: Approval for research

fundingRespected Mam,

I am pleased to inform you I am ready to provide you a grant of INR 7,50,000 towards following projects by your faculty

Title of the Project	Name of the Principal Investigator	Funds provided (INR in Lakhs)	Duration of the project
Evaluation of Cognitive Dysfunction in Recovered BipolarDisorder Patients Compared withBiological Marker	Dr Brijesh Saran	2.00	24 Months
Diagnosis of Schizophrenic withBiologiccal Marker and MRI	Dr Amoolya Seth	1.00	12 Months
Study of Spectrum of Lesions inBone Marrow Aspiration and Terphine Biopsy from a Tertiary Care Center	Dr Prem Garg	1.50	24 Months
Importance of Family Studies with High Performance LiquidChromotography (HPLC) in Hemoglobin Disorders	Dr Abhishek Pathre	1.50	24 Months

Various Medications Used for Gastritis among Post- operativePatients in Surgery IPD in a Tertiary Care Hospital	Dr Vivek TejvirYadav	1.50	18 Months

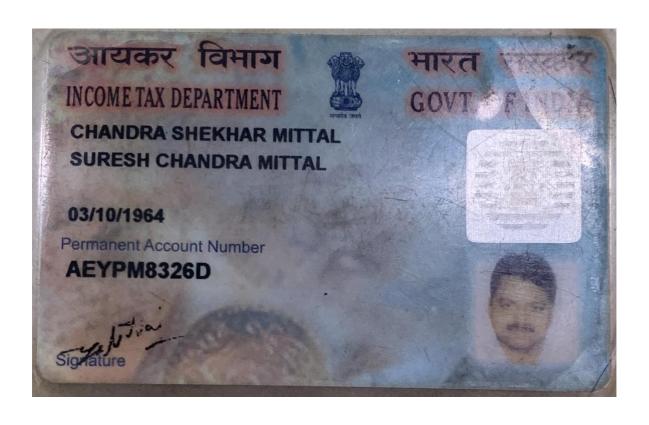
Please share with me the full proposals within 30 days of receiving this letter. Further, please submit a copy of final project report post completion as well as the outcome/impact of the project.

Thank you and regards.

Chandra Shekhar Mittal (Authorized Signatory)

# CC to:

- 1. Dr Brijesh Saran
- 2. Dr Amoolya Seth
- 3. Dr Prem Garg
- 4. Dr Abhishek Pathre
- 5. Dr Vivek Tejvir Yadav







चन्द्र शेखर मित्तल Chandra Shekhar Mittal DOB: 03-10-1964

Gender:Male



9144 6343 0065

आधार - आम आदमी का अधिकार



# विशिष्ट पहचान प्रा

S/O स्रेश चन्द्र मित्तल, एसआरबी-पास, ज्ञान खण्ड-३, इन्दिराप्रम, शिप्रा सन सिटी, गाजियाबाद, उत्तर प्रदेश, 201014

#### Address:

S/o Suresh Chandra Mittal, Srb-36 ३६ ए, शिपा रिवेरा, सेंट थोमस स्कूल वेह A, Shipra Riviera, Near St. Thomas School, Gyan Khand-3, Indirapuram, Shipra Sun City, Ghaziabad, Uttar Pradesh, 201014



1800 300 1947

help@uidai.gov.in

www www.uidai.gov.in

P.O. Box No. 1947, Bengaluru-560 001

Date: 26/07/2021

To,

Dr. Jyoti Batra

Dean Research

Santosh Deemed to be University

Subject: Request for research funding

#### Respected Mam,

We have received a request from your side for a research grant to conduct medical/dental research in various departments. We have received your proposals and revert back after review committee's decision.

S.No.	Title	Name of Principal investigator
1.	Prevalence of Selenium deficiency among pregnant females in District Ghaziabad- a cross-sectional study	Dr Anupama Singh
2.	Impact of Selenium deficiency on birth outcomes in pregnant females- A case-control study	Dr Deepika Agrawal
3.	lodine deficiency and its associated factors among pregnant women in District Ghaziabad- a cross-sectional study	Dr Anupama Singh
4.	Rheumatoid arthritis and its associated factors among adult population of District Ghaziabad- a comparative study	Dr Deepika Agrawal

Mr Mithun Malik

(Authorized Signatory)

To,

Dr. Jyoti Batra

Dean Research

Santosh Deemed to be University

Subject: Approval for research funding

Respected Mam,

I am pleased to inform you after thorough discussion with you and your faculty members, I am ready to fund the following research projects worth a sum of INR 5,00,000.

S.No.	Title	Name of Principal investigator	Amount (INR in Lakhs)	Study duration
1.	Prevalence of Selenium deficiency among pregnant females in District Ghaziabad- a cross- sectional study	Dr Anupama Singh	1.00	24 Months
2.	Impact of Selenium deficiency on birth outcomes in pregnant females- A case-control study	Dr Deepika Agrawal	1.00	12 Months
3.	lodine deficiency and its associated factors among pregnant women in District Ghaziabad- a cross-sectional study	Dr Anupama Singh	1.00	12 Months
4.	Rheumatoid arthritis and its associated factors among adult population of District Ghaziabad- a comparative study	Dr Deepika Agrawal	2.00	12 Months

Please share with me the full proposals within 30 days of receiving this letter. Further, please submit a copy of final project report post completion.

Thank you and regards.

Mr Mithun Malik

(Authorized Signatory)







Date: 08/07/2021

To,

Dr. Jyoti Batra

Dean Research

Santosh Deemed to be University

Subject: Request for research funding

## Respected Mam,

We have received a request from your side for a research grant to conduct medical/dental research in various departments. We have received your proposals and revert back after review committee's decision.

S.No	Name of the Project, Clinical Trial, Endowment, Chairs	Name of the Principal Investigator/Co Investigator	
1	Epidemiology, clinical characteristics and outcome of confirmed covid19 cases presented to the emergency department	Dr Manish Sabbarwal	
2	Local Drug Delivery System in Osteomyelitis Search for Novel Antibiotic Combinations Covering Common Orthopaedic Flora - A Pharmacoclinical Study	Dr Apporva Agarwal	
3	Estimation of Serum Pseudocholinesterase in Acute Organo Phosphate Poisoning and its Correlation to Mortality	Dr Vishwajeet Singh	
4	Trends of Serum Alkaline Phosphatase in Post- Menopausal Females and its Relation to BMD, Response to Osteopenia Treatment	Dr Amit Dwivedi	
5	A study to assess the minimal clinically important difference (MCID) and minimal detectable change (MDC) in the functional ability of patients with chronic low back pain (CLBP) undergoing multimodal physical therapy treatment.	Dr Rajeev Anand	
6	Variation of Harmonics to Noise Ratio from the Age Range of 9-18 Years Old in both the Genders	Dr Vineet Gupta	
7	A case control study to assess lipoprotein-a and PAI-1 in women with polycystic ovary syndrome	Dr Jyoti Batra, Dr Rinku Garg	
8	Morphometric analysis and types of articular facets on human dry tali and calcanei of North Indian origin	Dr Swati Yadav	

9	Virtual Anthropology: Useful Radiological Tools for Age Assessment in Clinoical Forensic Medicine and Toxicology	Dr Shilpa Singh
10	Regulation of Calcium Homeostasis in Acute Kidney Injury: A Prospective Observational Study	Dr Rohit Bhagat
11	Role of Intravenous Tranexamic Acid in Reducing Blood Loss during Caesarean Delivery	Dr Gunjan Gulati Bhagat
12	A cross sectional survey on physical fitness, mental health and associated factors in mothers of children with special needs	Dr Rani Srivastava
13	Chest computed tomography in immunocompromised patients with COPD	Dr Ashish Kumar Shukla

Mohit Gupta (Authorized Signatory)

To,

Dr. Jyoti Batra

Dean Research

Santosh Deemed to be University

Subject: Approval for research funding

## Respected Mam,

I am pleased to inform you I am ready to provide you a grant of INR 3,70,000 towards following projects by your faculty

S.No	Name of the Project, Clinical Trial, Endowment, Chairs	Name of the Principal Investigator/Co Investigator	Department of Principal Investigator / Co Investigator	Funds provided (INR in Lakhs)	Duration of the project
1	Epidemiology, clinical characteristics and outcome of confirmed covid19 cases presented to the emergency department	Dr Manish Sabbarwal	Faculty of Medicine	0.10	24 Months
2	Local Drug Delivery System in Osteomyelitis Search for Novel Antibiotic Combinations Covering Common Orthopaedic Flora - A Pharmacoclinical Study	Dr Apporva Agarwal	Faculty of Medicine	0.10	3 months
3	Estimation of Serum Pseudocholinesterase in Acute Organo Phosphate Poisoning and its Correlation to Mortality	Dr Vishwajeet Singh	Faculty of Medicine	0.20	3 months
4	Trends of Serum Alkaline Phosphatase in Post-Menopausal Females and its Relation to BMD, Response to Osteopenia Treatment	Dr Amit Dwivedi	Faculty of Medicine	0.20	3 months

5	A study to assess the minimal clinically important difference (MCID) and minimal detectable change (MDC) in the functional ability of patients with chronic low back pain (CLBP) undergoing multimodal physical therapy treatment.	Dr Rajeev Anand	Faculty Medicine	of	0.20	3 months
6	Variation of Harmonics to Noise Ratio from the Age Range of 9-18 Years Old in both the Genders	Dr Vineet Gupta	Faculty Medicine	of	0.30	3 months
7	A case control study to assess lipoprotein-a and PAI-1 in women with polycystic ovary syndrome	Dr Jyoti Batra, Dr Rinku Garg	Faculty Medicine	of	0.20	3 months
8	Morphometric analysis and types of articular facets on human dry tali and calcanei of North Indian origin	Dr Swati Yadav	Faculty Medicine	of	0.20	3 months
9	Virtual Anthropology: Useful Radiological Tools for Age Assessment in Clinoical Forensic Medicine and Toxicology	Dr Shilpa Singh	Faculty Medicine	of	0.10	3 months
10	Regulation of Calcium Homeostasis in Acute Kidney Injury: A Prospective Observational Study	Dr Rohit Bhagat	Faculty Medicine	of	0.35	3 months
11	Role of Intravenous Tranexamic Acid in Reducing Blood Loss during Caesarean Delivery	Dr Gunjan Gulati Bhagat	Faculty Medicine	of	0.20	3 months
12	A cross sectional survey on physical fitness, mental health and associated factors in mothers of children with special needs	Dr Rani Srivastava	Faculty Medicine	of	0.10	3 months
13	Chest computed tomography in immunocompromised patients with COPD	Dr Ashish Kumar Shukla	Faculty Medicine	of	1.45	24 months

Please share with me the full proposals within 30 days of receiving this letter. Further, please submit a copy of final project report post completion as well as the outcome/impact of the project.

Thank you and regards.

**Mohit Gupta** (Authorized Signatory)

- 1. Dr Manish Sabbarwal
- 2. Dr Apporva Agarwal
- 3. Dr Vishwajeet Singh
- 4. Dr Amit Dwivedi
- 5. Dr Rajeev Anand
- 6. Dr Vineet Gupta
- 7. Dr Jyoti Batra, Dr Rinku Garg
- 8. Dr Swati Yadav
- 9. Dr Shilpa Singh
- 10.Dr Rohit Bhagat
- 11.Dr Gunjan Gulati Bhagat
- 12.Dr Rani Srivastava
- 13.Dr Asahish Kumar Shukla







Date: 26/07/2021

To,

Dr. Jyoti Batra

Dean Research

Santosh Deemed to be University

Subject: Request for research funding

Respected Mam,

We have received a request from your side for a research grant to conduct medical/dental research in various departments. We have received your proposals and revert back after review committee's decision.

S.No.	Title	Name of Principal investigator
1.	A Study of Estimation of Stature by Anthropometric Measurements of Head	Dr Shilpa Singh

Mr Mohit Aggarwal

(Authorized Signatory)

To,

Dr. Jyoti Batra

Dean Research

Santosh Deemed to be University

Subject: Approval for research funding

Respected Mam,

I am pleased to inform you after thorough discussion with you and your faculty members, I am ready to fund the following research projects worth a sum of INR 1,00,000.

S.No.	Title	Name of Principal investigator	Amount (INR in Lakhs)	Study duration
1.	A Study of Estimation of Stature by Anthropometric Measurements of Head	Dr Shilpa Singh	1	12 Months

Please share with me the full proposals within 30 days of receiving this letter. Further, please submit a copy of final project report post completion.

Thank you and regards.

Mr Mohit Aggarwal

(Authorized Signatory)

CC to:

1. Dr Shilpa Singh

# आयकर विभाग INCOME TAX DEPARTMENT



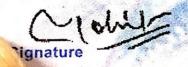
## भारत सरकार GOVT. OF INDIA

MOHIT AGGARWAL

**BHARAT BHUSHAN AGGARWAL** 

19/05/1991
Permanent Account Number

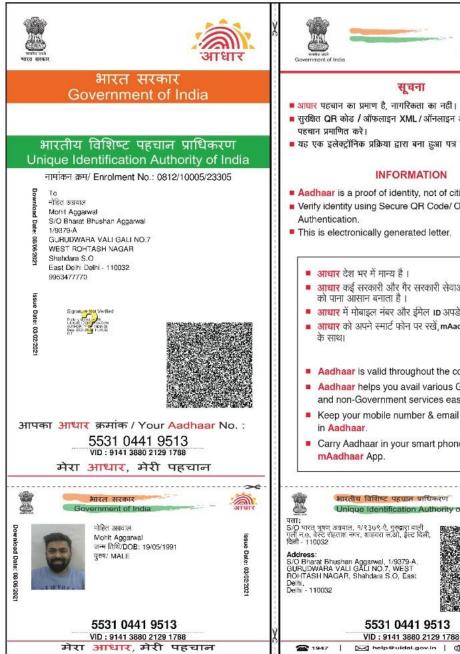
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լ help@uldai.gov.in | ∰ www.uldai.gov.in

Date: 08/07/2021

To,

Dr. Jyoti Batra

Dean Research

Santosh Deemed to be University

Subject: Request for research funding

Respected Mam,

We have received a request from your side for a research grant to conduct medical/dental research in various departments. We have received your proposals and revert back after review committee's decision.

SNo	Title	Name of the Principal Investigator/Co Investigator
1.	NSAIDs preferred among NVD - episiotomy Females attending O & G Department	Dr Shaktibala Dutta
2.	Comparing Efficacy of Teriparatide, Zolendronic Acid and Alendronate with BMD Recovery Trend in Patients Treated for Bone Quality Enhancement	Dr Nishit Palo
3.	Clinicoetiological Study of Dermatophytes	Dr V.K. Garg

Rupali Bisht

(Authorized Signatory)

To,

Dr. Jyoti Batra

Dean Research

Santosh Deemed to be University

Subject: Approval for research funding

Respected Mam,

I am pleased to inform you after thorough discussion with you and your faculty members, I am ready to fund the following research projects worth a sum of INR 5,00,000.

SNo	Title	Name of the Principal Investigator/Co Investigator	Funds provided (INR in Lakhs)	Duration of the project
1.	NSAIDs preferred among NVD - episiotomy Females attending 0 & G Department	Dr Shaktibala Dutta	1.00	24 Months
2.	Comparing Efficacy of Teriparatide, Zolendronic Acid and Alendronate with BMD Recovery Trend in Patients Treated for Bone Quality Enhancement	Dr Nishit Palo	2.00	24 Months
3.	Clinicoetiological Study of Dermatophytes	Dr V.K. Garg	2.00	24 Months

Please share with me the full proposals within 30 days of receiving this letter. Further, please submit a copy of final project report post completion.

Thank you and regards.

Rupali Bisht (Authorized Signatory)

- 1. Dr Shaktibala Dutta
- 2. Dr Nishit Palo
- 3. Dr V.K. Garg





Date: 22/06/2021

To,

Dr. Jyoti Batra

Dean Research

Santosh Deemed to be University

Subject: Request for research funding

Respected Mam,

We have received a request from your side for a research grant to conduct medical/dental research in various departments. We have received your proposals and revert back after review committee's decision.

S.No	Name of the Project	Name of the Principal Investigator/Co Investigator
1	The Pattern of Arterial Supply of human Brain & its Variations As Seen In "Magnetic Resonance Angiography of Brain" in North Indian population	Dr Nisha Kaul
2	Immunomorphological pattern of regional lymphs nodes and role of angiogenesis mast cells in oral squamous cell carcinoma	Dr Shweta Chaudhary
3	Clinicoetiological Study of Sexually Transmitted Disease in a Tertiary Care Hospital	Dr Sameer Mishra
4	Acute pain abdomen in the emergency department- clinical characteristics and outcome, a prospective observational study.	Dr Manish Sabbarwal
5	Use of Inravenous-Gadolinilum-based Contrast Media in Patients with Kidney Disease	Dr Ashish Kr Shukla
6	Increasing Opportunities for Trainees of Santosh Radiology Department to engage in Global Health Radiology: Radiology Training	Dr Sumit Kumar Ghosh
7	Spectrum of CECT abdomen findings in patients of acute abdomen in a tertiary care hospital	Dr Sarthak Kesarwani
8	Role of inflammatory markers in Prognosis of COVID - 19	Dr Ritu Jain, Dr Rinku Garg
9	Assessment of psychopathology in Medical Students using internet	Dr Ravindra Kumar Bansal
10	Prevalence of childhood depression and anxiety in senior secondary class students	Dr Brijesh Saran
11	Age Estimation by Radiographic Appearance of Root Development of Mandibular Third Molar	Dr Vishwajeet Singh

Sangam Aggarwal (Authorized Signatory)

To,

Dr. Jyoti Batra

Dean Research

Santosh Deemed to be University

Subject: Approval for research funding

Respected Mam,

I am pleased to inform you I am ready to provide you a grant of INR 2,25,000 towards following projects by your faculty.

S.No	Name of the Project	Name of the Principal Investigator/Co Investigator	Funds provided (INR in Lakhs)	Duration of the project
1	The Pattern of Arterial Supply of human Brain & its Variations As Seen In "Magnetic Resonance Angiography of Brain" in North Indian population	Dr Nisha Kaul	0.20	3 months
2	Immunomorphological pattern of regional lymphs nodes and role of angiogenesis mast cells in oral squamous cell carcinoma	Dr Shweta Chaudhary	0.20	3 months
3	Clinicoetiological Study of Sexually Transmitted Disease in a Tertiary Care Hospital	Dr Sameer Mishra	0.20	3 months
4	Acute pain abdomen in the emergency department- clinical characteristics and outcome, a prospective observational study.	Dr Manish Sabbarwal	0.20	3 months
5	Use of Inravenous-Gadolinilum-based Contrast Media in Patients with Kidney Disease	Dr Ashish Kr Shukla	0.30	3 months
6	Increasing Opportunities for Trainees of Santosh Radiology Department to engage in Global Health Radiology: Radiology Training	Dr Sumit Kumar Ghosh	0.15	3 months
7	Spectrum of CECT abdomen findings in patients of acute abdomen in a tertiary care hospital	Dr Sarthak Kesarwani	0.15	3 months
8	Role of inflammatory markers in Prognosis of COVID -19	Dr Ritu Jain, Dr Rinku Garg	0.25	3 months
9	Assessment of psychopathology in Medical Students using internet	Dr Ravindra Kumar Bansal	0.20	3 months

10	Prevalence of childhood depression and anxiety in senior secondary class students	Dr Brijesh Saran	0.20	3 months
11	Age Estimation by Radiographic Appearance of Root Development of Mandibular Third Molar	Dr Vishwajeet Singh	0.20	3 months

Please share with me the full proposals within 30 days of receiving this letter. Further, please submit a copy of final project report post completion as well as the outcome/impact of the project.

Thank you and regards.

Sangam Aggarwal (Authorized Signatory)

- 1. Dr Nisha Kaul
- 2. Dr Shweta Chaudhary
- 3. Dr Sameer Mishra
- 4. Dr Manish Sabbarwal
- 5. Dr Ashish Kr Shukla
- 6. Dr Sumit Kumar Ghosh
- 7. Dr Sarthak Kesarwani
- 8. Dr Ritu Jain, Dr Rinku Garg
- 9. Dr Ravindra Kumar Bansal
- 10.Dr Brijesh Saran
- 11.Dr Vishwajeet Singh







## A-905, Omicron-1, Greater Noida, Uttar Pradesh - 201308

Ref. No.:-SF/JUL/17/2021 Date:-17/07/2021

## **Research Grant Approval Letter**

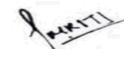
Dr. Srishti Aggarwal,
Faculty
Dermatology
Santosh Medical College and Hospital
Santosh Deemed to be University Ghaziabad, U.P.

Dear Dr. Srishti Aggarwal,

We are pleased to inform you that your application regarding approval of funding grant for the Research project titled "A comparative analysis of treatment response with tofacitinib, oral corticosteroids and methotrexate in Alopecia areata." for 3 months has been considered for funding grants by our Expert Committee after review.

The above said project is hereby approved by the Competent Authority and sanctioned total amount of Rs.25,000/- (Twenty Five thousand).

Thank you and Regards



(Authorized Signatory)

- 1) Dean Research, Santosh University, Ghaziabad, UP
- 2) Office copy

Date: 22/06/2021

To,

Dr. Jyoti Batra

Dean Research

Santosh Deemed to be University

Subject: Request for research funding

Respected Mam,

We have received a request from your side for a research grant to conduct medical/dental research in various departments. We have received your proposals and revert back after review committee's decision.

S.No	Name of the Project	Name of the Principal Investigator/Co Investigator	
1	The Pattern of Arterial Supply of human Brain & its Variations As Seen In "Magnetic Resonance Angiography of Brain" in North Indian population	Dr Nisha Kaul	
2	Immunomorphological pattern of regional lymphs nodes and role of angiogenesis mast cells in oral squamous cell carcinoma	Dr Shweta Chaudhary	
3	Clinicoetiological Study of Sexually Transmitted Disease in a Tertiary Care Hospital	Dr Sameer Mishra	
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9	Assessment of psychopathology in Medical Students using internet	Dr Ravindra Kumar Bansal	
10	Prevalence of childhood depression and anxiety in senior secondary class students	Dr Brijesh Saran	
11	Age Estimation by Radiographic Appearance of Root Development of Mandibular Third Molar	Dr Vishwajeet Singh	

Sangam Aggarwal (Authorized Signatory)

To,

Dr. Jyoti Batra

Dean Research

Santosh Deemed to be University

Subject: Approval for research funding

Respected Mam,

I am pleased to inform you I am ready to provide you a grant of INR 2,25,000 towards following projects by your faculty.

S.No	Name of the Project	Name of the Principal Investigator/Co Investigator	Funds provided (INR in Lakhs)	Duration of the project
1	The Pattern of Arterial Supply of human Brain & its Variations As Seen In "Magnetic Resonance Angiography of Brain" in North Indian population	Dr Nisha Kaul	0.20	3 months
2	Immunomorphological pattern of regional lymphs nodes and role of angiogenesis mast cells in oral squamous cell carcinoma	Dr Shweta Chaudhary	0.20	3 months
3	Clinicoetiological Study of Sexually Transmitted Disease in a Tertiary Care Hospital	Dr Sameer Mishra	0.20	3 months
4	Acute pain abdomen in the emergency department- clinical characteristics and outcome, a prospective observational study.	Dr Manish Sabbarwal	0.20	3 months
5	Use of Inravenous-Gadolinilum-based Contrast Media in Patients with Kidney Disease	Dr Ashish Kr Shukla	0.30	3 months
6	Increasing Opportunities for Trainees of Santosh Radiology Department to engage in Global Health Radiology: Radiology Training	Dr Sumit Kumar Ghosh	0.15	3 months
7	Spectrum of CECT abdomen findings in patients of acute abdomen in a tertiary care hospital	Dr Sarthak Kesarwani	0.15	3 months
8	Role of inflammatory markers in Prognosis of COVID -19	Dr Ritu Jain, Dr Rinku Garg	0.25	3 months
9	Assessment of psychopathology in Medical Students using internet	Dr Ravindra Kumar Bansal	0.20	3 months

10	Prevalence of childhood depression and anxiety in senior secondary class students	Dr Brijesh Saran	0.20	3 months
11	Age Estimation by Radiographic Appearance of Root Development of Mandibular Third Molar	Dr Vishwajeet Singh	0.20	3 months

Please share with me the full proposals within 30 days of receiving this letter. Further, please submit a copy of final project report post completion as well as the outcome/impact of the project.

Thank you and regards.

Sangam Aggarwal (Authorized Signatory)

- 1. Dr Nisha Kaul
- 2. Dr Shweta Chaudhary
- 3. Dr Sameer Mishra
- 4. Dr Manish Sabbarwal
- 5. Dr Ashish Kr Shukla
- 6. Dr Sumit Kumar Ghosh
- 7. Dr Sarthak Kesarwani
- 8. Dr Ritu Jain, Dr Rinku Garg
- 9. Dr Ravindra Kumar Bansal
- 10.Dr Brijesh Saran
- 11.Dr Vishwajeet Singh





Date: 08/07/2021

To,

Dr. Jyoti Batra

Dean Research

Santosh Deemed to be University

Subject: Request for research funding

Respected Mam,

We have received a request from your side for a research grant to conduct medical/dental research in various departments. We have received your proposals and revert back after review committee's decision.

S.No.	Title	Name of Principal investigator
1	Oral health indicators of oral health related quality of life among Indian elderly: A cross-sectional study	Dr Mansi Singh, Dr Priyanka Bhushan
2	A randomized, double-blind clinical trial was to evaluate the effect of preoperative administration of intraligamentary injections of diclofenac sodium and dexamethasone on the anesthetic efficacy of 2% lidocaine given as an inferior alveolar nerve block in the endodontic management of symptomatic irreversible pulpitis	Dr Nidhi Gupta, Dr Neeti Mittal
3	A study to evaluate and compare the accuracy of two age estimation methods in Indian children by using the open apex method proposed by Cameriere et al and the London Atlas of Tooth Development.	Dr Natasha Gambhir
4	An assessment of the incidence of postoperative pain, treatment time and analgesic intake after single visit endodontic treatment of mandibular molars using XP-endo Shaper, 2Shape and ProTaper Gold rotary systems.	Dr Deepika Yadav
5	Effect of nonsurgical periodontal therapy on gingival crevicular fluid levels of Interleukin-35 in patients with periodontitis	Dr Aruna Nautiyal
6	A study to assess the impact of age on osteometric mesaurements of patella.	Dr Sumit Tellewar
7	Influence of Parenting Styles and Peer Attachment on Life Satisfaction Among Adolescents: Mediating Role of Self-Esteem	Dr Parul Gairola

8	A randomised controlled trial to evaluate the anaesthetic efficacy of 2% lidocaine with different concentrations of epinephrine (1:80,000 and 1:200,000) in intraligamentary injection after a failed primary inferior alveolar nerve block	Dr Manoj Goyal
9	The pattern of road accident and trauma iin Ghaziabad	Dr. Manish Sabbharwal
10	Effect of addition on dexmedetomidine on local anesthesia efficacy: a randomised controlled trial	Dr Neeti Mittal
11	Relability of Self evaluation of treatment needs index for endodontic intervention	Dr Chetna Arora

NewSingh

Neel Singh (Authorized Signatory)

Date: 16/02/2022

Τo,

Dr. Jyoti Batra

Dean Research

Santosh Deemed to be University

Subject: Approval for research funding

Respected Mam,

I am pleased to inform you I am ready to provide you a grant of INR 6,00,000 towards following projects by your faculty.

S.No.	Title	Name of Principal investigator	Funds Provided (INR in Lakhs)	Duration of the Project
1	Oral health indicators of oral health related quality of life among Indian elderly: A cross-sectional study	Dr Mansi Singh, Dr Priyanka Bhushan	0.30	3 months
2	A randomized, double-blind clinical trial was to evaluate the effect of preoperative administration of intraligamentary injections of diclofenac sodium and dexamethasone on the anesthetic efficacy of 2% lidocaine given as an inferior alveolar nerve block in the endodontic management of symptomatic irreversible pulpitis	Dr Nidhi Gupta, Dr Neeti Mittal	0.50	6 Months
3	A study to evaluate and compare the accuracy of two age estimation methods in Indian children by using the open apex method proposed by Cameriere et al and the London Atlas of Tooth Development.	Dr Natasha Gambhir	0.45	6 Months
4	An assessment of the incidence of postoperative pain, treatment time and analgesic intake after single visit endodontic treatment of mandibular molars using XP-endo Shaper, 2Shape and ProTaper Gold rotary systems.	Dr Deepika Yadav	0.55	6 Months
5	Effect of nonsurgical periodontal therapy on gingival crevicular fluid levels of Interleukin-35 in patients with periodontitis	Dr Aruna Nautiyal	1.45	24 months
6	A study to assess the impact of age on osteometric mesaurements of patella.  Page 24	Dr Sumit Tellewar 6 of 335	0.20	3 Months

7	Influence of Parenting Styles and Peer Attachment on Life Satisfaction Among Adolescents: Mediating Role of Self-Esteem	Dr Parul Gairola	0.15	3 Months
8	A randomised controlled trial to evaluate the anaesthetic efficacy of 2% lidocaine with different concentrations of epinephrine (1:80,000 and 1:200,000) in intraligamentary injection after a failed primary inferior alveolar nerve block	Dr Manoj Goyal	0.60	6 Months
9	The pattern of road accident and trauma in Ghaziabad	Dr. Manish Sabbharwal	0.65	6 Months
10	Effect of addition on dexmedetomidine on local anesthesia efficacy: a randomised controlled trial	Dr Neeti Mittal	0.75	6 Months
11	Relability of Self evaluation of treatment needs index for endodontic intervention	Dr Chetna Arora	0.40	6 Months

Please share with me the full proposals within 30 days of receiving this letter. Further, please submit a copy of final project report post completion as was the outcome/impact of the project.

Thank you and regards.

Nud Singh Neel Singh (Authorized Signatory)

- 1. Dr Mansi Singh, Dr Priyanka Bhushan
- 2. Dr Nidhi Gupta, Dr Neeti Mittal
- 3. Dr Natasha Gambhir
- 4. Dr Deepika Yadav
- 5. Dr Aruna Nautiyal
- 6. Dr Sumit Tellewar
- 7. Dr Parul Gairola
- 8. Dr Manoj Goyal
- 9. Dr Manish Sabbarwal
- 10.Dr Neeti Mittal
- 11.Dr Chetna Arora





Date: 12/07/2021

To,

Dr. Jyoti Batra

Dean Research

Santosh Deemed to be University

Subject: Request for research funding

Respected Mam,

We have received a request from your side for a research grant to conduct medical/dental research in various departments. We have received your proposals and revert back after review committee's decision.

S.No	Name of the Project, Clinical Trial, Endowment, Chairs	Name of the Principal Investigator/Co Investigator		
1	Fixed dexmedetomidine infusion versus fixed-dose midazolam bolus as primary sedative for maintaining intra-procedural sedation during endobronchial ultrasound-guided transbronchial needle aspiration: a double blind randomized controlled trial	Dr Suveer Sharma		
2	Influence of epidural ropivacaine with or without dexmedetomidine on postoperative analgesia and patient satisfaction after thoraco-lumbar spine instrumentation: a randomized, comparative, and double-blind study	Dr Mahima Lakhanpal		
3	A retrospective cohort study to investigate the effect of smoking on rates of progressive visual field (VF) damage over time in glaucoma	Dr Priya Singh		
4	A study to check the reliability of human dental pulp for identification of gender using Barr bodies.	Dr Shobroze Tantray		
5	The effect of Neonicotinoid on Chick Embryos and its development	Dr. Yogesh Yadav		
6	An invirto study was to evaluate the accuracy of the apex locator in the presence of different irrigating solutions	Dr Avdesh Sharma		
7	A randomised controlled trial to assess the efficacy of holistic approaches (naturopathy and yoga) alone as well as in combination with pharmacological therapy in the treatment of chronic orofacial pain of non-odontogenic origin	Dr Swati Verma, Dr Priyanka Bhushan		
8	A prospective, cluster-randomized, examiner-masked, 3-arm trial to evaluate the efficacy of time outdoors per school day over 2 years on myopia onset and shift.	Dr Sarita Agrawal		
		Violan Bhatt		

Viplav Bhatt (Authorized Signatory)

To,

Dr. Jyoti Batra

Dean Research

Santosh Deemed to be University

Subject: Approval for research funding

Respected Mam,

I am pleased to inform you I am ready to provide you a grant of INR 5,00,000 towards following projects by your faculty

S.No	Name of the Project, Clinical Trial, Endowment, Chairs	Name of the Principal Investigator/Co Investigator	Department of Principal Investigator/ Co Investigator	Funds provided (INR in Lakhs)	Duration of the project
1	Fixed dexmedetomidine infusion versus fixed-dose midazolam bolus as primary sedative for maintaining intra-procedural sedation during endobronchial ultrasound-guided transbronchial needle aspiration: a double blind randomized controlled trial	Dr Suveer Sharma	Faculty of Medicine	0.40	6 Months
2	Influence of epidural ropivacaine with or without dexmedetomidine on postoperative analgesia and patient satisfaction after thoraco-lumbar spine instrumentation: a randomized, comparative, and double-blind study	Dr Mahima Lakhanpal	Faculty of Medicine	0.30	6 Months
3	A retrospective cohort study to investigate the effect of smoking on rates of progressive visual field (VF) damage over time in glaucoma	Dr Priya Singh	Faculty of Medicine	0.40	6 Months
4	A study to check the reliability of human dental pulp for identification of gender using Barr bodies.	Dr Shobroze Tantray	Faculty of Dentistry	0.70	6 Months
5	The effect of Neonicotinoid on Chick Embryos and its development	Dr. Yogesh Yadav	Faculty of medicine	0.70	6 Months
6	An invirto study was to evaluate the accuracy of the apex locator in the presence of different irrigating solutions	Dr Avdesh Sharma	Faculty of Dentistry	0.85	12 months

7	A randomised controlled trial to assess the efficacy of holistic approaches (naturopathy and yoga) alone as well as in combination with pharmacological therapy in the treatment of chronic orofacial pain of nonodontogenic origin	Dr Swati Verma, Dr Priyanka Bhushan	Faculty of Dentistry	1.35	24 months
8	A prospective, cluster- randomized, examiner- masked, 3-arm trial to evaluate the efficacy of time outdoors per school day over 2 years on myopia onset and shift.	Dr Sarita Agrawal	Faculty of Medicine	0.30	3 months

Please share with me the full proposals within 30 days of receiving this letter. Further, please submit a copy of final project report post completion as well as the outcome/impact of the project.

Thank you and regards.

Viplav Bhatt (Authorized Signatory)

- 1. Dr Suveer Sharma
- 2. Dr Mahima Lakhanpal
- 3. Dr Priya Singh
- 4. Dr Shobroze Tantray
- 5. Dr. Yogesh Yadav
- 6. Dr Avdesh Sharma
- 7. Dr Swati Verma, Dr Priyanka Bhushan
- 8. Dr Sarita Agrawal







### Clinical Trial Details (PDF Generation Date :- Tue, 28 Mar 2023 10:26:03 GMT)

**CTRI Number Last Modified On Post Graduate Thesis** 

Type of Trial

Type of Study

**Study Design Public Title of Study** 

Scientific Title of Study

26/04/2022 No

CTRI/2021/05/033791 [Registered on: 25/05/2021] - Trial Registered Prospectively

Interventional Drug

Randomized, Parallel Group, Active Controlled Trial

A Clinical Trial Evaluating Niclosamide for the Treatment of Covid-19 Disease.

A Multicentric Phase II Randomized Open Label Clinical Study to Evaluate Efficacy Safety and Tolerability of Niclosamide for the Treatment of Hospitalized Corona Virus Disease (COVID-19) **Patients** 

Secondary IDs if Any

Secondary ID	Identifier
ICS/LAX/2020-006 Version 3.0 Dated 28 Mar	Protocol Number
2021	

**Details of Principal** Investigator or overall **Trial Coordinator** (multi-center study)

Details of Principal Investigator		
Name	Dr R M Chhabra	
Designation	Medical Monitor/Trial Coordinator	
Affiliation	Insignia Clinical Services Pvt. Ltd.	
Address	Insignia Clinical Services Pvt. Ltd. Room # 512, Clinical Trial Division, Clinical Operations Department, Best Sky Tower, Netaji Subhash Place, Pitampura North West Delhi, India Not Applicable North West DELHI 110034 India	
Phone	011-49049115	
Fax	011-49049115	
Email	Chhabradrrm@gmail.com	

**Details Contact** Person (Scientific Query)

Details Contact Person (Scientific Query)		
Name	Dr R M Chhabra	
Designation	Medical Monitor/Trial Coordinator	
Affiliation	Insignia Clinical Services Pvt. Ltd.	
Address	Insignia Clinical Services Pvt. Ltd. Room # 512, Clinical Trial Division, Clinical Operations Department, Best Sky Tower, Netaji Subhash Place, Pitampura North West Delhi, India Not Applicable North West DELHI 110034 India	
Phone	011-49049115	
Fax	011-49049115	
Email	Chhabradrrm@gmail.com	

**Details Contact** Person (Public Query)

		-	
	Details Contact Person (Public Query)		
Name Dr R M Chhabra			
	Designation	Medical Monitor/Trial Coordinator	
	Affiliation Insignia Clinical Services Pvt. Ltd.		
Address Insignia Clinical Services Pvt. Ltd. Room # 512, Clinical Trial Division, Clinical Operations Department, Best Sky Tower, Neta		Division, Clinical Operations Department, Best Sky Tower, Netaji Subhash Place, Pitampura North West Delhi, India Not Applicable	



	DELHI 110034 India
Phone	011-49049115
Fax	011-49049115
Email	Chhabradrrm@gmail.com

# **Source of Monetary or Material Support**

### **Source of Monetary or Material Support**

> Laxai Life Sciences Pvt. Ltd. Third Floor, Ventureast Plaza, Plot # 40 & 41, Road No. 02, Financial District, Nanakramguda, Ranga Reddy District, Telangana 500032 India

### **Primary Sponsor**

Primary Sponsor Details		
Name	Laxai Life Sciences Pvt Ltd	
Address	Third Floor, Ventureast Plaza, Plot # 40 & 41, Road No. 02, Financial District, Nanakramguda, Ranga Reddy District, Telangana 500032 India	
Type of Sponsor	Pharmaceutical industry-Indian	

### **Details of Secondary Sponsor**

Name	Address
	Uppal Road, IICT Colony, Tamaka, Hyderabad, Telangana 500007
CSIRIICT	

### Countries of Recruitment

### **List of Countries**

India

### Sites of Study

ndia			
Name of Principal Investigator	Name of Site	Site Address	Phone/Fax/Email
Dr A Thumjaa	Aarupadai Veedu Medical College and Hospital	Ground Floor, Department of Paediatrics, Aarupadai Veedu Medical College and Hospital, Kirumampakkam, Puducherry- 607403 Pondicherry PONDICHERRY	914132615246 thumjaa@gmail.com
Dr B L Shashi Bhushan	Bangalore Medical College and Research Institute	Room No 50 B Block Department of Pulmonary Medicine Victoria Hospital Fort KR Road Bangalore KARNATAKA	080-26701150 ShashiBhushanBL@Ya hoo.com
Dr Aneesh Raj	Noorul Islam Institute of Medical Science (NIMS) and Research Foundation	Covid Care Center, Aush Block , NIMS Medicity, Aralummoodu P.O. Neyyattinkara, Trivandrum, Kerala-695123 Thiruvananthapuram KERALA	04712222115 draneeshraj@gmail.co m
Dr Pravin Soni	PCMCs PGI Yashwant Rao Chavan Memorial Hospital	Covid Blocks 64A Ground Floor and 111 First Floor PCMCs PGI Yashwant Rao Chavan Memorial Hospital Sant Tukaram Nagar, Pimpri, Pune 411018 Pune	020-67332200 020-67332200 DrPravinSoni18@Gmail .com



		MAHARASHTRA	
Dr Vijaykumar Barge	RCSM Government Medical College and CPR Hospital	Room 01, Department of Medicine, Dasara Chowk, Bhausingji Road, Town Hall, Kolhapur 416012 Kolhapur MAHARASHTRA	0231-2644233 0231-2644233 DrVijayBarge12@Gmail .com
Dr Ashok Kumar	Santosh Medical College Hospital	First Floor, Department of General Medicine, Santosh Medical College Hospital #1, Ambedkar Road Ghaziabad, UTTAR PRADESH Ghaziabad UTTAR PRADESH Ghaziabad UTTAR PRADESH	0120-2741141 0120-2741141 SMCHGZB@Gmail.co m
Dr Vishal Gupta	SMS Medical College & Attached Hospital	Room # 04, PRT Wing, Dhanwantri Block, SMS Medical College & Attached Hospital Jaipur RAJASTHAN	020-67332222 DrVishalGuptaMD@Re diffmail.com
Dr Changalva Premdeep	Vijaya Super Speciality Hospital	Ground Floor, Room No. 7 Department of Pulmonology, Vijaya Super Speciality Hospital, 16-II/41 A Raghava Cine Complex Road, Pogathota, Nellore, Andhra Pradesh-524001, India Nellore ANDHRA PRADESH	08612321828 dr.premdeep88@gmail. com

### Details of Ethics Committee

	l		
Name of Committee	Approval Status	Date of Approval	Is Independent Ethics Committee?
Ethics Committee of Bangalore Medical College & Research Institute	Approved	18/06/2021	No
Ethics Committee SMS Medical College Jaipur	Approved	14/07/2021	No
Institutional Ethics Committee, Yashwantrao Chavan Memorial Hospital, Pimpri, Pune, Maharashtra	Approved	14/07/2021	No
Institutional Human Ethical Committee Aarupadai Veedu Medical College and Hospital	Approved	11/11/2021	No
NIMS IEC	Approved	12/10/2021	No
Rajarshee Chhatarpati Shahu Maharaj Govt Medical College and	Approved	14/07/2021	No



### **PDF of Trial** CTRI Website URL - http://ctri.nic.in

Chhatarpati Pramila Raje Hospital, Kolhapur Institutional Ethics Committee 2			
Society for Academic, Scientific & Translational Research Advancement	Approved	20/05/2021	Yes
Society for Academic, Scientific & Translational Research Advancement	Approved	20/05/2021	Yes
Vijaya Ethics Committee	Approved	17/01/2022	No

**Regulatory Clearance** Status from DCGI

Status Date Approved/Obtained 20/04/2021

**Health Condition / Problems Studied** 

Health Type	Condition
	Coronavirus as the cause of diseases classified elsewhere
Patients	Other specified respiratory disorders

Intervention / **Comparator Agent** 

Туре	Name	Details	
Intervention	Niclosamide 2000 mg orally Plus Standard of Care	Niclosamide 2000 mg orally Plus Standard of Care Treatment Duration for 07 Days	
Comparator Agent	Standard Of Care	Standard Of Care	

### **Inclusion Criteria**

Inclusion Criteria		
Age From	18.00 Year(s)	
Age To	65.00 Year(s)	
Gender	Both	
Details	Male & female (non-pregnant, non-lactating, post-menopausal, surgically sterilized, or practicing a reliable surgically sterilized, or practicing a reliable method of birth control during the duration of the study) patients with ages ranging from 18 to 65 years (both inclusive). style Condition for at least 6 months before enrollment. condition for at least 6 months before enrollment. confirmed diagnosis of moderate COVID-19 symptoms demonstrated by: style Positivity in RT-PCR 2019-nCov test on respiratory tract (nasopharyngeal / oropharyngeal) specimens. spo2 < 93% (range 90-93%) on room air, Respiratory Rate > 24 and < 30 breaths per minute. Patients with SpO2 < 90% to be excluded from the study. style > cbr/> Signs of pneumonia (lung injury/lung involvement) confirmed by Chest X-Ray at the time of study entry. spo7/> cbr/> Disease severity score between Grade 4 to 5 on the WHO 9-point ordinal scale & patient requires hospitalization for management of the disease. spo7/> within 7 days from symptom onset or within 72 hours of laboratory diagnosis of SARS-CoV2 via RT-PCR test. spo7/> br/> Able to take oral tablets at the time of study entry and agree not to participate in any other study for study for study entry informed consent for participation in the study and willing to adhere to all protocol procedures. In case the subject is unable to provide informed consent then the same should be obtained from a legally acceptable representative (LAR). str/> cbr/> br/> br/> br/> cbr/>	

**Exclusion Criteria** 

	Exclusion Criteria
Details	Subjects will be excluded from the study for any of the following



### PDF of Trial CTRI Website URL - http://ctri.nic.in

#### reasons:

Subjects with known allergy or hypersensitivity to Niclosamide or any of its components.

Patients who have previously had a disease severity score of 6 or 7 on the WHO 9-point ordinal scale.

Evidence of severe or critical illness, defined by at least 1 of the following:

Respiratory failure requiring at least 1 of the following:

Endotracheal intubation and mechanical ventilation, oxygen delivered by high flow nasal cannula

Extracorporeal membrane oxygenation (ECMO) or clinical diagnosis of respiratory failure

Shock (defined by systolic blood pressure (BP) 5times ULN].

Subjects with oxygen saturation (SpO2) ?90%.

Respiration Rate ?30 breaths per minute at the time of enrolment.

History of refractory nausea, vomiting, or chronic gastrointestinal disorders, inability to swallow the study drug, or having undergone extensive bowel resection which may affect adequate absorption of study medications.

Inability to swallow tablets (administration via nasogastric tube is permitted in patients who become unable to swallow after starting the study drug).

Patients who require IL-6 inhibitors for management of inflammation at the time of study entry.

Female subjects who are pregnant or involved in breastfeeding.

Subject was using adrenocorticosteroids (except topical or inhaled preparations) or immunosuppressive or immunomodulatory drugs (e.g., immunosuppressants, anticancer drugs, interleukins, interleukin antagonists, or interleukin receptor blockers) within one week prior to study entry.

Subject has a serious chronic disease (e.g., human immunodeficiency virus (HIV), hepatitis B virus or hepatitis C virus, cancer requiring chemotherapy within the preceding 6 months, unstable cardiac, pulmonary, neurologic, vascular, or endocrinologic disease states requiring medication dose adjustments within the last 30 days.

Has a history of alcohol or drug abuse in the previous 6 months.

Subject has a psychiatric disease that is not well controlled where controlled is defined as stable on a regimen for more than one year.

Subject already treated with another COVID 19 therapy but has relapsed with a positive diagnosis.

Hospital discharge is anticipated in ?24 hours.



Anticipated transfer to another hospital which is not a study site within 72 hours.

Participated in any other clinical trial or taken an investigational drug within 1 month.

### **Method of Generating Random Sequence**

Computer generated randomization

Method of Concealment Pre-numbered or coded identical Containers

Blinding/Masking **Primary Outcome** 

Open Label

Outcome	Timepoints
Time to Clinical Improvement of 2-points on WHO 8-Point Ordinal Scale	Baseline, Day 03, Day 05, Day 07, Day 14, Day 21

#### **Secondary Outcome**

Outcome	Timepoints
Secondary outcome measures for this study will include:	Time frame : 3, 7, 10, 14 days
Time to respiratory viral clearance	
	Time frame: Baseline, 14, 21 days
Improvement in lung injury on Chest X-Ray	Time frame: 21 days
Other outcome measures for this study will include:	
All-cause mortality	

### **Target Sample Size**

Total Sample Size=96

Sample Size from India=96

Final Enrollment numbers achieved (Total)=Applicable only for Completed/Terminated trials Final Enrollment numbers achieved (India)=Applicable only for Completed/Terminated trials

**Phase of Trial** 

**Date of First** 

01/06/2021

**Enrollment (India)** 

Phase 2

**Date of First Enrollment (Global)**  No Date Specified

**Estimated Duration of Trial** 

Years=0 Months=6 Days=0

**Recruitment Status of** Trial (Global)

Not Applicable

**Recruitment Status of** Trial (India)

Closed to Recruitment of Participants

**Publication Details** 

NIL

**Brief Summary** 

This is a Phase II, Randomized, Multi-centric, Open Label clinical study to evaluate the efficacy, safety & tolerability of Niclosamide when used alongside Standard of Care (SOC) for the treatment of hospitalized patients with coronavirus disease (COVID-19).

The proposed study is a two phase clinical study wherein first phase, i.e, Treatment Phase will began when either a male or female (non-pregnant, non-lactating) patients between 18 to 65 years (both inclusive) with clinically confirmed & documented diagnosis of moderate coronavirus disease (COVID-19) with severity rating of Grade 4 or Grade 5 at the time of study entry as per WHO ordinal score and who require hospitalization for management of the disease will be screened and enrolled for participation in the study as per study protocol.

# ICMR - National Institute of Medical Statistics



### **PDF of Trial** CTRI Website URL - http://ctri.nic.in

The treatment period with investigational product in test group will be 7 days. It is however necessary that all patients in either test or control groups be allowed to take concomitant SOC as per the prescribed schedule for entire duration of the study, as applicable. Follow-up Phase shall begin from EOT (Day 8) and will continue for another 2 weeks for each patient. During Follow-up Phase, all patients in both test and/or control groups will take SOC as advised per individual treatment plan and will be asked to monitor signs & symptoms of disease, status of clinical recovery and adverse events, if any.

# INSIGNIA CLINICAL SERVICES PVT LTD (from 1-Apr-22) SANTOSH HOSPITAL( ASHOK KUMAR)

Ledger Account

### 1-Apr-22 to 4-Mar-24

Date	Particulars		Vch Type	Vch No.	Debit	Credit
1-Apr-22 Dr	r Opening Balance					2,62,125.00
19-Apr-22	Cr STATE BANK OF INDIA		Payment	74	1,25,190.00	
21-Apr-22	Cr STATE BANK OF INDIA		Payment	82	1,12,500.00	
	Dr STATE BANK OF INDIA		Receipt	7		1,12,500.00
29-Apr-22	Cr STATE BANK OF INDIA		Payment	107	1,12,500.00	
2-May-22	Cr STATE BANK OF INDIA		Payment	139	11,138.00	
3-Feb-23	AGAINST INVOIC RS 37125 Dr (as per details)		Journal	431		1,94,400.00
	Ec Fees ( Hypertension) TDS PAYABLE U/S 94J 01001 TO 01082	2,16,000.00 Dr 21,600.00 Cr				
19-Mar-23	Cr STATE BANK OF INDIA		Payment	1410	1,36,080.00	
					4,97,408.00	5,69,025.00
Cr	Closing Balance				71,617.00	
					5,69,025.00	5,69,025.00

# INSIGNIA CLINICAL SERVICES PVT LTD (from 1-Apr-22)

# Santosh Hospital Ghazibad

Ledger Account

### 1-Apr-22 to 4-Mar-24

						Page 1
Date	Particulars		Vch Type	Vch No.	Debit	Credit
1-Apr-22 D	r Opening Balance					8,39,347.00
2-May-22	Cr STATE BANK OF INDIA 30 PERCENT P NICLOSAMIDE	AYMENT	Payment	138	66,217.00	
6-Jun-22	Cr STATE BANK OF INDIA 30% payment co	olcochine	Payment	259	1,10,472.00	
3-Feb-23	Dr (as per details)		Journal	432		7,24,797.00
	Ec Fees (Hypertension) TDS PAYABLE U/S 94J 01001 TO 0108	,	3.00 Cr			
19-Mar-23	Cr STATE BANK OF INDIA		Payment	1408	2,50,000.00	
	Cr STATE BANK OF INDIA		Payment	1409	2,50,000.00	
С	r Closing Balance				6,76,689.00 8,87,455.00	15,64,144.00
					15,64,144.00	15,64,144.00



### Clinical Trial Details (PDF Generation Date :- Tue, 28 Mar 2023 10:25:32 GMT)

**CTRI Number Last Modified On Post Graduate Thesis** 

Type of Trial Type of Study

**Study Design Public Title of Study** 

Scientific Title of Study

Secondary IDs if Any

CTRI/2021/04/032555 [Registered on: 06/04/2021] - Trial Registered Prospectively

26/10/2022

No

Interventional

Drug

Randomized, Parallel Group Trial

A Clinical Trial to Assess the Efficacy, Safety and tolerability of Colchicine for Covid-19 Disease Treatment in Indian Patients.

A prospective, pilot, clinical trial to evaluate the efficacy and safety of Colchicine for improvement of clinical outcomes during Coronavirus (COVID-19) disease treatment in high-risk Indian patients.

Secondary ID Identifier ICS/LAX/2021-001 Version 1.0 Dated 18 Jan Protocol Number

**Details of Principal** Investigator or overall **Trial Coordinator** (multi-center study)

	Details of Principal Investigator		
Name	Dr R M Chhabra		
Designation	Medical Monitor/Trial Coordinator		
Affiliation	Insignia Clinical Services Pvt. Ltd.		
Address	Insignia Clinical Services Pvt. Ltd. Room # 512, Clinical Trial Division, Clinical Operations Department, Best Sky Tower, Netaji Subhash Place, Pitampura North West, DELHI 110034, India North West DELHI 110034 India		
Phone	011-49049115		
Fax	011-49049115		
Email	Chhabradrrm@gmail.com		

**Details Contact** Person (Scientific Query)

Details Contact Person (Scientific Query)		
Name	Dr R M Chhabra	
Designation	Medical Monitor/Trial Coordinator	
Affiliation	Insignia Clinical Services Pvt. Ltd.	
Address	Insignia Clinical Services Pvt. Ltd. Room # 512, Clinical Trial Division, Clinical Operations Department, Best Sky Tower, Netaji Subhash Place, Pitampura North West, DELHI 110034, India North West DELHI 110034 India	
Phone	011-49049115	
Fax	011-49049115	
Email	Chhabradrrm@gmail.com	

**Details Contact** Person (Public Query)

	Details Contact Person (Public Query)		
)	Name	Dr R M Chhabra	
	Designation	Medical Monitor/Trial Coordinator	
	Affiliation	Insignia Clinical Services Pvt. Ltd.	
	Address	Insignia Clinical Services Pvt. Ltd. Room # 512, Clinical Trial Division, Clinical Operations Department, Best Sky Tower, Netaji Subhash Place, Pitampura North West, DELHI 110034, India North West	





	DELHI 110034 India
Phone	011-49049115
Fax	011-49049115
Email	Chhabradrrm@gmail.com

### Source of Monetary or Material Support

### Source of Monetary or Material Support

> Laxai Life Sciences Pvt Ltd Third Floor, Ventureast Plaza, Plot # 40 & 41, Road No. 2, Financial District, Nanakramguda, Ranga Reddy District, Telangana 500032 India

### **Primary Sponsor**

Primary Sponsor Details		
Name	Laxai Life Sciences Pvt Ltd	
Address  Third Floor, Ventureast Plaza, Plot No. 40 and 41, Road N Financial District, Nanakramguda, Ranga Reddy District, 1 - 500032 India		
Type of Sponsor	Pharmaceutical industry-Indian	

### **Details of Secondary Sponsor**

Name	Address
	Uppal Rd, IICT Colony, Tarnaka, Hyderabad, Telangana 500007
Technology CSIRIICT	

# Countries of Recruitment

### **List of Countries**

India

### Sites of Study

	india			
Name of Principal Investigator	Name of Site	Site Address	Phone/Fax/Email	
Dr R N Sechassayana	Aarupadai Veedu Medical College and Hospital	Ground Floor, Department of Paediatrics, Aarupadai Veedu Medical College and Hospital, Kirumampakkam, Puducherry- 607403 Pondicherry PONDICHERRY	914132615246 narayanassamyseshas sayanan28@gmail.com	
Dr B L Shashi Bhushan	Bangalore Medical College and Research Institute	Room No 50 B Block Department of Pulmonary Medicine Victoria Hospital Fort KR Road Bangalore KARNATAKA	080-26701150 ShashiBhushanBL@Ya hoo.com	
Dr Sushila Kataria	Medanta - The Medicity	Department of Internal Medicine Division Internal Medicine Room No 30 Sector - 38, Gurgaon, Haryana 122001 India Gurgaon HARYANA	0124-4141414 0124-4834111 Mukul.Manchanda@Me danta.org	
Dr Aneesh Raj	Noorul Islam Institute of Medical Science (NIMS) and Research Foundation	Aush Block , NIMS	04712222115 draneeshraj@gmail.co m	



Dr Pravin Nagulal Soni	PCMC PGI Yashwantrao Chavan Memorial Hospital	Room 01 Third Floor Department of Medicine PCMC PGI Yashwantrao Chavan Memorial Hospital Sant Tukaran Nagar Vallabhnagar Pimpri Pune Pune MAHARASHTRA	020-67332222 DrPravinSoni18@Gmail .com
Dr Vijaykumar Barge	RCSM Government Medical College and CPR Hospital	Room 01, Department of Medicine, Dasara Chowk, Bhausingji Road, Town Hall, Kolhapur 416012 Kolhapur MAHARASHTRA	0231-2644233 0231-2644233 DrVijayBarge12@Gmail .com
Dr Shivani Bansal	Santosh Medical College Hospital	Fifth Floor, Covid Ward, Santosh Medical College Hospital#1, Ambedkar Road Ghaziabad, UTTAR PRADESH Ghaziabad UTTAR PRADESH	0120-2741141 0120-2741141 smchgzb@gmail.com
Dr Vishal Gupta	SMS Medical College & Attached Hospital	Room # 04, PRT Wing, Dhanwantri Block, SMS Medical College & Attached Hospital Jaipur RAJASTHAN	0141-2518370 DrVishalGuptaMD@Re diffmail.com
Dr Changalva Premdeep	Vijaya Super Speciality Hospital	Ground Floor, Room No. 7 Department of Pulmonology, Vijaya Super Speciality Hospital, 16-II/41 A Raghava Cine Complex Road, Pogathota, Nellore,-524001 Nellore ANDHRA PRADESH	08612321828 dr.premdeep88@gmail. com

### Details of Ethics Committee

Name of Committee	Approval Status	Date of Approval	Is Independent Ethics Committee?
Ethics Committee for Human Research	Submittted/Under Review	No Date Specified	No
Ethics Committee of Bangalore Medical College & Research Institute	Approved	18/06/2021	No
Ethics Committee SMS Medical College Jaipur	Approved	14/07/2021	No
Institutional Ethical Committee Vinayaka Missions Medical College	Approved	11/11/2021	No
Institutional Ethics Committee Vinayaka Missions Kirupananda	Approved	11/11/2021	No



Variyar Medical College and Hospitals			
Institutional Ethics Committee, Govt. Medical College Govt. General Hospital	Approved	23/06/2021	No
Institutional Human Ethical Committee Aarupadai Veedu Medical College and Hospital	Approved	11/11/2021	No
Medanta Institutional Ethics Committee	Approved	15/06/2021	No
NIMS IEC	Approved	12/10/2021	No
PGMCs PGI YCMH Ethics Committee	Approved	04/05/2021	No
Rajarshee Chhatarpati Shahu Maharaj Govt Medical College and Chhatarpati Pramila Raje Hospital, Kolhapur Institutional Ethics Committee 2	Approved	14/07/2021	No
Society for Academic, Scientific & Translational Research Advancement	Approved	31/03/2021	Yes
Vijaya Ethics Committee	Approved	17/01/2022	No

Regulatory Clearance Status from DCGI

Health Condition / Problems Studied

Status	Date
Approved/Obtained	05/02/2021

Health Type	Condition
Patients	Coronavirus as the cause of diseases classified elsewhere
Patients	Other specified respiratory disorders

Intervention /
Comparator Agent

Туре	Name	Details
Intervention	Colchicine 0.5mg tablets plus Standard of Care	Colchicine 0.5mg tablets plus Standard of Care Dose 0.5 mg, Frequency BID, Route of Administration Oral, Duration of Therapy 28 Days
Comparator Agent	Standard of Care	Standard of Care

### **Inclusion Criteria**

Inclusion Criteria		
Age From	40.00 Year(s)	
Age To	65.00 Year(s)	
Gender	Both	
Details	Subjects meeting all the following criteria will be included in the study: study:   Study:   Study:	



### PDF of Trial CTRI Website URL - http://ctri.nic.in

respiratory tract (nasopharyngeal / oropharyngeal) specimens.<br/> b.Presence of clinical features of dyspnea and/or hypoxia, fever, cough, including SpO2 < 94% (range 90-94%) on room air, Respiratory Rate > 24 and < 30 breaths per minute.<br/> <br/> 4. Significant COVID-19 symptoms, and judged by the treating doctor to be at high risk of progression to severe category due to presence of any of the following:<br/>
<br/>
a.Having at least one of the high-risk criteria, i.e., obesity (BMI ? 30 kg/m2), diabetes mellitus, uncontrolled hypertension (diastolic blood pressure > 90 mm Hg systolic blood pressure ?150 mm Hg), known respiratory disease (including asthma or chronic obstructive pulmonary disease), known heart failure, known coronary disease; <br/> b.Demonstrating signs of cardiac injury due to Elevated troponin level, <br/> <br/> <br/> 5.Patients who require hospitalization for control of disease at the time of study entry. <br/> <br/> <br/> 6.Within 7 days from symptom onset or within 48 hours of laboratory diagnosis of SARS- CoV2.<br/>
<br/>
- 7.Able to take oral tablets and agreeing not to participate in any other study for duration of participation in this study. <br/> <br/> <br/> 8.Willing to sign voluntary informed consent for participation in the study and willing to adhere to all protocol procedures. In case the subject is unable to provide informed consent than the same should be obtained from legally acceptable representative (LAR).<br/>br/>

#### **Exclusion Criteria**

#### **Exclusion Criteria**

#### **Details**

- 1. History of present illness (will be based on treating physician's opinion)
- a. Neurological and neurodevelopmental disorders.
- b.Congenital heart disease
- c. Severe heart disease or a history of clinically significant arrhythmias which may affect participants safety (According to the ECG or medical history). Corrected QT interval of 450 milliseconds or higher (according to the Bazett formula) on a 12 lead surface ECG / Abnormal ECG (to eliminate concerns that a potential interaction between colchicine and hydroxychloroquine could lead to excess QT prolongation)
- 2.Requirement of oxygen supplementation greater than 8L nasal cannula at the time of enrollment.
- 3. Treating physician clinical judgement that the patient will require mechanical respiratory support within 24 hours.
- 4. Patient currently in Septic shock or with hemodynamic instability requiring vasopressors.
- 5. History of cirrhosis.
- 6.A subject undergoing hemodialysis.
- 7. Severe gastrointestinal failure, severe gastrointestinal disorders, or stomach ulcer.
- 8. Patient is currently taking colchicine for other indications (gout or Familial Mediterranean Fever).
- 9. Patient with inflammatory bowel disease (Crohns disease or ulcerative colitis), chronic diarrhea or malabsorption
- 10. Severe Hepatic Insufficiency (ALT or AST greater than 5 times ULN) or Renal Failure (eGFR using the MDRD equation for all



subjects less than 30 mL per min).

- 11. Patient received Remdesivir, Sarilumab, Tocilizumab, Lopinavir, Ritonavir or other immunomodulator given for COVID-19 treatment prior to study entry.
- 12.Patient is on (and cannot discontinue) a strong CYP3A4 inhibitor (e.g. clarithromycin, indinavir, itraconazole, ketoconazole, nefazodone, nelfinavir, ritonavir, saquinavir, telithromycin, atazanavir), a moderate CYP3A4 inhibitor (e.g. diltiazem, verapamil, fluconazole, amprenavir, aprepitant, fosamprenavir) or a Pgp Inhibitor (e.g. cyclosporine, ranolazine).
- 13. Patients who may require IL 6 inhibitors as per clinical judgment of the investigator for management of inflammation at the time of study entry.
- 14. Pregnant or lactating women women of a childbearing age with a positive pregnancy test

Method of Generating Random Sequence Computer generated randomization

Method of Concealment Pre-numbered or coded identical Containers

Blinding/Masking
Primary Outcome

Not Applicable

Outcome	Timepoints
Time to clinical improvement of 2-points on WHO 8-point ordinal scale	28 days (4 weeks)

#### **Secondary Outcome**

Outcome	Timepoints
Improvement in cardiac & biochemical inflammatory markers	28 days
Time to discharge from hospital	28 days
Rate of viral clearance	28 days
Patients requiring auxiliary oxygen therapy (non-invasive/invasive) & time on auxiliary oxygen therapy.	28 days
All-cause mortality.	28 days
Adverse events (Serious, Expected/Unexpected, Related/Non-Related).	28 days

**Target Sample Size** 

Total Sample Size=84

Sample Size from India=84

**Final Enrollment numbers achieved (Total)**=Applicable only for Completed/Terminated trials **Final Enrollment numbers achieved (India)**=Applicable only for Completed/Terminated trials

Phase of Trial Date of First Enrollment (India) Phase 2

Date of First

07/04/2021

Enrollment (Global)
Estimated Duration of

No Date Specified

Estimated Duration of Trial

Years=0 Months=6 Days=0 ICMR - National Institute of Medical Statistics



### PDF of Trial CTRI Website URL - http://ctri.nic.in

# INSIGNIA CLINICAL SERVICES PVT LTD (from 1-Apr-22)

# **Sundry Creditors**

Group Summary 1-Apr-23 to 4-Mar-24

		Page 1	
	Closing E	Closing Balance	
	Debit	Credit	
SANTOSH HOSPITAL( ASHOK KUMAR)		71,617.00	
SANTOSH HOSPITAL ( DR SHIVANI BANSAL )		<mark>44,100.00</mark>	
Santosh Hospital Ghazibad		8,87,455.00	
Grand Total		10,03,172.00	



## INDIA NON JUDICIAL

# Government of National Capital Territory of Delhi

# e-Stamp

Certificate No.

Certificate Issued Date

Account Reference

Unique Doc. Reference

Purchased by

Description of Document

Property Description

Consideration Price (Rs.)

First Party

Second Party

Stamp Duty Paid By

Stamp Duty Amount(Rs.)

: IN-DL71545171236776T

: 09-Apr-2021 04:10 PM

IMPACC (IV)/ dl895203/ DELHI/ DL-DLH

: SUBIN-DLDL89520343822448897302T

: INSIGNIA CLINICAL SERVICES PRIVATE LIMITED

Article 5 General Agreement

TRI-PARTITE CLINICAL TRIAL AGREEMENT

: 0\_

(Zero)

: INSIGNIA CLINICAL SERVICES PRIVATE LIMITED

: SANTOSH MEDICAL COLLEGE HOSPITAL GHAZIABAD AND DR

SHIVANI BANSAL

: INSIGNIA CLINICAL SERVICES PRIVATE LIMITED

500

(Five Hundred only)



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Professor And Hospital
Santosh Medical College And Hospital
Ghaziabad (U.P.)
MCI-25922



### सत्यमेव जयते

### Certificate No.

Certificate Issued Date

Account Reference

Unique Doc. Reference

Purchased by

Description of Document

Property Description

Consideration Price (Rs.)

First Party

Second Party

Stamp Duty Paid By

Stamp Duty Amount(Rs.)

# INDIA NON JUDICIAL

# Government of National Capital Territory of Delhi

## e-Stamp

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: IMPACC (IV)/ dl895203/ DELHI/ DL-DLH

: SUBIN-DLDL89520343824222656950T

: INSIGNIA CLINICAL SERVICES PRIVATE LIMITED

: Article 5 General Agreement

: TRI-PARTITE CLINICAL TRIAL AGREEMENT

: 0

(Zero)

: INSIGNIA CLINICAL SERVICES PRIVATE LIMITED

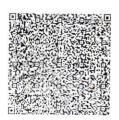
SANTOSH MEDICAL COLLEGE HOSPITAL GHAZIABAD AND DR

SHIVANI BANSAL

: INSIGNIA CLINICAL SERVICES PRIVATE LIMITED

· 100

(One Hundred only)



\_Please write or type below this line\_





Professor And Hospital

Professor And Hospital

Santosh Medical College (U.P.)

Santosh Medical College (U.P.)

MCI-25922

# CLINICAL TRIAL AGREEMENT BY/AND BETWEEN

# INSIGNIA CLINICAL SERVICES PRIVATE LTD., DELHI (CONTRACT RESEARCH ORGANIZATION)

AND

SANTOSH MEDICAL COLLEGE HOSPITAL, GHAZIABAD, (NCR DELHI) (TRIAL SITE)

AND

DR. SHIVANI BANSAL (PRINCIPAL INVESTIGATOR)

> AS OF (19<sup>th</sup> May 2021)

CRO CRO TRIAL SITE PRINCIPAL ENVESTIGATOR

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### **CLINICAL TRIAL AGREEMENT**

This Clinical Trial Agreement ("Agreement") is made as of this 19<sup>th</sup>day of May, 2021 (the "Effective Date") by and between:

1. INSIGNIA CLINICAL SERVICES PRIVATE LTD. (ICS), a company incorporated under the laws of India as registered under the Indian Companies Act, 2013 having its business address at Unit No. 512, 5th Floor, Best Sky Tower, Netaji Subhash Place, Pitampura, New Delhi-110034 (hereinafter referred to as "CRO") (which expression unless repugnant to the context includes its associates, administrators, successors in interest and permitted assigns) through Mr. Amardeep Singh, who has been authorized by M/s Laxai Life Sciences Pvt. Ltd.. (hereinafter referred to as "Sponsor") to execute this Agreement on behalf of CRO and Sponsor.

#### AND

2. SANTOSH MEDICAL COLLEGE HOSPITAL i.e. a world class, multispeciality, Teaching and Training Hospital at No.1, Ambedkar Road, Ghaziabad - 201 001 (U.P.) (herein after referred to as "Trial Site") owned and managed by Santosh Trust (which expression unless repugnant to the context includes its associates, administrators, successors in interest and permitted assigns) through Dr. Alpana Agrawal who has been authorized to execute this Agreement on behalf of Trial Site.

#### AND

3. Dr. Shivani Bansal (hereinafter referred to as the "Principal Investigator" or "PI"), an independent consultant / employee of the Trial Site, who has been appointed as Principal Investigator for the purpose of conducting clinical trial at Trial Site.

(The "CRO", "Trial Site" and "Principal Investigator" are hereinafter individually referred to as a "Party", and collectively as "Parties")

#### WHEREAS:

A. ICS is a Delhi-based Contract Research Organization ("CRO") providing services primarily in India, directly or through its affiliates, associates, agents and subsidiaries. The major activities conducted by ICS include design, setup and management of clinical studies with human beings for the owners and / or manufacturers of pharmaceutical products, medical devices and food supplements / nutraceuticals.

Dr. Shavani Bansal

M.D. (Medicine)

Professor

Santosh Medical Gollege And Hospital

Ghaziadad (U.P.)

MCI-25922

TRIAL SITE PRINCIPAL INVESTIGATOR

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- B. Laxai Life Sciences Pvt. Ltd. (Sponsor) is a pharmaceutical company engaged in the development of pharmaceutical product and desires to carry out a clinical trial involving study drug "Colchicine Tablets 0.5 mg", according the Protocol Title: A prospective, pilot, clinical trial to evaluate the efficacy and safety of COLchicine for improvement of clinical outcomes during COrona Virus (COVID-19) disease treatment in high-risk Indian patients. [Acronym: COLCOVIN Study] (herein after referred to as 'Study') incorporated herein by reference as Exhibit- A and all subsequent amendments thereto;
- C. Sponsor has appointed CRO to manage the Study and assist Sponsor with site selection, management services for conduct of clinical trials at Trial Site and determine the safety and efficacy of Sponsor's product through submission of allinformation/documentation provided by Principal Investigator to the CRO under the Agreement;
- D. CRO and Trial Site are related through a Memorandum of Understanding ("MoU") dated 19<sup>th</sup> October 2020 for conduct of such Clinical Studies at the Trial Site. This Agreement will be an extension to the said MoU and will cover specific aspects related to terms and conditions of arrangements between CRO, Trial Site and Principal Investigator for the purposes of successful execution of the Study at the Trial Site.
- E. The Principal Investigator is a qualified medical practitioner and has been engaged by the Trial Site to participate in the study as an investigator and is responsible to conduct the study, the detailed statement issued by Trial Site attached hereto as Exhibit—C working with the Trial Site and has agreed to conduct the Study at the Trial Site only after the prior written approval of Institutional Review Board/Independent Ethics Committee("IRB/IEC") at the Trial Site.
- F. The Trial Site is a medical facility qualified and equipped with adequate resources to undertake the study and the Trial Site and Principal Investigatorhave agreed to perform the study on the terms and conditions hereinafter setforth.

NOW, THEREFORE in consideration of the premises and the mutual promises and covenants express herein the Parties agree as flows:

# 1. SCOPE OF THE AGREEMENT

1.1 Trial Site and Principal Investigator will undertake an sponsored clinical trial ("Study") described in Exhibit-A, i.e. study of drug "Colchicine Tablets 0.5 mg", according the Protocol Title:A prospective, pilot, clinical trial to evaluate the efficacy and safety of COLchicine for improvement of clinical outcomes during COronaVirus (COVID-19)

disease treatment in high-risk <u>IN</u>dian patients. [Acronym: COLCOVIN Study]. The Study will be conducted by the Trial Site under the direction of Principal Investigator.

- 1.2 In the event of any conflict between the terms and conditions of this Agreement and the Protocol or between this Agreement and any of its Exhibits, the terms and conditions of the Protocol shall control with respect to matters of the clinical conduct of the Study, and the terms of this Agreement shall control with respect to all other matters.
- 1.3 Unless otherwise agreed to by the Parties, Sponsor and/or CRO will provide to the Trial Site on a timely basis, without charge, the required quantities of properly-labelled Sponsor drug(s) or biologics(s) and other materials (e.g., Principal Investigator's brochure, handling and storage instructions, and, if applicable, placebo) necessary for Trial Site to conduct the Study in accordance with the protocol. Unless stated otherwise in writing by CRO, all such items are and will remain the sole property of CRO/Sponsor until administered or dispensed to Study subjects during the course of the Study. Receipt, storage, and handling of Study drug will be in compliance with all applicable laws and regulations, and CRO's or Sponsor's instructions.
- 1.4 CRO, Trial Site and Principal Investigator shall comply with and conduct all aspects of the Study in compliance with all applicable laws and regulations, including generally accepted standards of good clinical practice relating to exportation of technical data, computer software, laboratory prototypes, and other commodities as applicable. Trial Site and Principal Investigator will only allow individuals who are appropriately trained and qualified to assist in the conduct of the Study.
- 1.5 Trial Site shall obtain approval (if any) for this Study and proof thereof shall be provided to CRO. Trial Site shall obtain from each subject, prior to the subject's participation in the Study, a signed informed consent and necessary authorization to disclose health information to CRO and/or Sponsor in a form approved in writing by the CRO or a waiver of consent as directed by the CRO and further provided that the informed consent is consistent with Trial Site policies.

### 2. PERFORMANCE OF THE STUDY:

2.1 Compliance with the Agreement: The purpose of this Agreement is to conduct the Study at the Trial Site. The protocol has been sponsored by the Sponsor and is approved by / or is subject to the approval of the Drug Controller General of India ("DCGI") under the Drugs & Cosmetics Act, 1940 including any amendments thereof (hereinafter referred as "Drugs & Cosmetics Act, 1940") and / or any other law or rules for the time being in force in India as well as approved by the Ethics Committee ("EC"). In the event the protocol is amended,

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such change shall be notified and if required under the law, prior approval of DCGI and/or EC shall be obtained. The Trial Site and the Principal Investigator agree to perform the Study in strict compliance with the protocol and terms and conditions of this Agreement including any amendments thereto. The Principal Investigator shall perform the Study at the study site of the institution. The Trial Site and Principal Investigator further represent, warrant and covenant that the Principal Investigator is and at all times, during the term of this Agreement, shall be (a) in good professional standing, (b) in possession of all requisite professional licenses, approval and permissions, (c) full qualified to conduct the study and to act as Principal Investigator under this Agreement, (d) fully experienced and knowledgeable with respect to all matters pertaining to the study and (e) responsible for supervision of all persons who may assist the Principal Investigator or otherwise be engaged in the Study. In the event that the Trial Site and/or the Principal Investigator use the services of sub-investigator, investigational staff, or other to conduct the Study pursuant to this Agreement, the Principal Investigator and Trial Site shall be responsible that all are appropriately licensed and credentialed and shall conduct the study in compliance with the terms and conditions of this Agreement. The Trial Site and PI shall be liable for any breach of such agreement by such individuals.

- 2.2 Replacement of Principle Investigator: In the event the Principal Investigator is unable to continue, either on account of his death or early termination of engagement from Trial Site or becoming incapacitated., in such circumstances, the Trial Site shall provide a written notice to CRO within three (3) calendar days of becoming aware of Principal Investigator's inability to continue. The Sponsor/CRO shall then appoint the Co-Investigator as a party to this Agreement by way of amendment/novation to this Agreement. In case the Sponsor/CRO terminate this Agreement, the Trial Site shall take all necessary steps to accommodate the decision.
- 2.3 Delegation of Duties: The Principal Investigator will personally supervise the Study and may not delegate this duty to any other individual without Sponsor/ CRO's prior written approval. Principal Investigator may delegate other duties as necessary to their investigators and qualified personal in accordance with regulatory requirement and upon notice to sponsor/CRO. The Trial Site may not replace the Principal Investigator without Sponsor's/CRO's prior written approval. If the Principal Investigator is to be temporarily absent from the Trial Site, the Trial Site shall designate an investigator qualified and trained to assume such responsibilities to temporarily supervise/continue the Study on behalf of Principal Investigator. All such designation of responsibility will be reported to Sponsor/ CRO in writing and DCGI and/or EC prior to its commencement.



- 2.4 Investigator and Staff Training: The Trial Site and Principal Investigator shall insure that other investigators and designated staff attend all Study related training conducted by Sponsor/CRO.
- 2.5 Use of Study drug: CRO shall provide the Study drug and all related document and any material wherever require for conduct of Study. Neither the Principal Investigator not Trial Site shall make use of Study drug, Study related documents and materials, for purposes other than performance of the Study in accordance of the protocol and this Study. The Principal Investigator and Trial Site shall account for and return to CRO or otherwise dispose of in accordance with CRO's Instruction any unused Study drug, materials and equipments and confidential information provided for the purposes of the Study. In case of destruction of Study drug at Trial Site, the Trial Site shall promptly provide certificate of such destruction. This provision does not apply to the documents that should be maintained and retained in secure manner by the Principal Investigator at the Trial Site as per study protocol, the Agreement and/or applicable guidelines laws and regulations.
- 2.6 Adverse Event Reporting: Principal Investigator and Trial Site also agrees to report to Licensing Authority as defined in Clause 3(2) (i), (ii),(iv) of New Drugs and Clinical Trials Rules, 2019 including any amendments thereof, Ethics Committee and CRO immediately, but not later than 24 hours or within such mandatory timelines as amended from time to time and specifically mentioned hereabove, After learning of any adverse event and all other important medical events, including but not limited to adverse reactions, as identified in the protocol, affecting any Study subject. Principal Investigator and Trial Site further agree to follow up such report with detailed written reports in compliance with all applicable legal and regulatory requirements.
- 2.7 Additional Research: Trial Site and Principal Investigator shall not conduct any additional research nor facilitate any third party to conduct any such research on study subject during the study or biological samples collected from Study subjects during the Study, data derived from the Study without prior written concern of Sponsor and CRO.

# 3. TRIAL DRUG; MATERIALS TRANSFER; RECORDS RETENTION; INSPECTION:

3.1 Trial Site and Principal Investigator acknowledge that the trial drug/device is owned or controlled by Sponsor/CRO and that neither the terms of this Agreement nor the protocol, nor any activities conducted by Trial Site or Principal Investigator for the trial/Study, shall be construed to grant to either Trial Site or Principal Investigator any rights in or to the compound.

- 3.2 Except as otherwise agreed by the Parties, CRO will provide the compound and any control/placebo material to be administered to trial subjects as part of the trial (collectively, the "Trial Drug") free of charge to Trial Site for administering or dispensing solely by or under the supervision of Principal Investigator or sub-investigator to trial subjects at the Trial Site in strict compliance with the protocol.
- 3.3 Trial Site and Principal Investigator shall use the Trial Drug solely to conduct the Trial in strict compliance with the protocol and for no other purpose, and shall not transfer the Trial Drug to any third parties. Trial Site and Principal Investigator shall handle, store, ship and dispose of the Trial Drug as directed by Sponsor/CRO or its designee and in compliance with all applicable laws, rules and regulations.
- 3.4 Trial Site and Principal Investigator will ensure that empty and partially used Trial Drug container and any Trial Drug remaining at the trial close-out visit at the Trial Site or upon early termination of this Agreement are disposed of or returned to CRO in accordance with the protocol.
- 3.5 Neither support of the trial, nor Trials Site's participation in the trial, impose any obligation, express or implied, on Trial Site or Principal Investigator to purchase, prescribe, provide favorable formulary status for or otherwise support Sponsor's/CRO's products.
- 3.6 Unless required by the Protocol, Trial Site will not modify the Trial Drug or its container. If the Trial Site policy requires any modification to the Trial Drug container, such modification must be approved in advance in writing by Sponsor/CRO.

## 4. RECORDS MAINTENANCE AND RETENTION:

- 4.1 The Trial Site and Principal Investigator shall prepare and maintain records, reports and Data provided in the Protocol, Ethics Committee (EC) requirements, and in accordance with all applicable laws and regulations. Trial Site or Principal Investigator shall cooperate with the Sponsor/CRO in making records, reports and Data developed under this Agreement.
- 4.2 Trial Site or Principal Investigator shall ensure the storage of data related to Study in accordance with the requirements of current Good Clinical Practices, in suitable and secured storage facilities and under appropriate conditions, for a period of time required under the Agreement, applicable laws and regulations in India or until 5 years after completion of all regulatory activity, whichever period is longer, unless to the extent that Sponsor/CRO requires the return or destruction of this data, in which case this request shall be complied with to the extent allowed by applicable laws and regulations. Before the destruction or deletion of such data, Sponsor/CRO's written approval shall be obtained.

CRO TRIAL SITE PRINCIPAL AND PRINCIPAL PRINCIP

### 5. PAYMENTS:

- 5.1 Budget and Compensation: The compensation and fees to be paid by the Sponsor/CRO for this Study is contained in the budget described in Exhibit- B attached hereto and incorporated by reference in this Agreement. Payment shall be due and payable in accordance with the schedule set forth in Exhibit- B.
- 5.2 Fair Market Value: The Party's acknowledge that the compensation and support provided by the Sponsor/CRO to the Trial Site, subject to provision of this Agreement represents the fair market value for the research service conducted by Trial Site and the Principal Investigator has been negotiated in an arm's length transaction, and has been determined in a manner that takes into account the volume or value of any reference or other business otherwise generated between the Sponsor/CRO and the situation are the principal investigator. The Parties acknowledge that the budget amounts represent an equitable exchange for the conduct of the Study in light of the professional time and expenses required for the performance of the Study.
- 5.3 Third Party Pay or Billing: Neither the Trial Site nor the Principal Investigator shall bill any third party for the Study of the Trial Drug or any other item or services furnished by the Sponsor/CRO in connection with the Study, or any services provided to subjects in connection with the Study for which payment is made as part of the Study except as may be specifically authorised by compensation standard set forth in Exhibit-B.
- 5.4 No part of any consideration paid hereunder are a prohibited payment for the recommending or arranging of the referral of business or the ordering of item of services; nor are the payments intended to include illegal referrals of business Nothing contained in this Agreement shall be construed connected in any manner as an obligation or inducement for the Trial Site or Principal Investigator to recommend that any person or entity purchase Sponsor's/CRO's product or those of any entity affiliated with the Sponsor/CRO.

### 6. TERM & TERMINATION:

- 6.1 This term of this Agreement shall commence upon the Effective Date and terminate upon the completion of the Parties' Study-related activities under the Agreement, unless terminated early as further described in this section.
- 6.2 This Agreement will become effective after it is fully executed and signed by all the Parties hereto and shall continue in effect for the full duration of the Study according to the protocol unless extended or sooner terminated in accordance with the provisions of this Agreement.

- 6.3 Unless earlier terminated in accordance with the provisions of this Agreement, the term of this Agreement shall commence on the Effective Date and shall terminate 6 months after completion of Study at Trial Site (hereinafter known as "Expiration Date"). The term of this Agreement shall commence upon the Effective Date and terminate upon the completion of the Parties' Study-related activities under the Agreement, unless terminated early as further described in this section.
- 6.4 CRO has the right to terminate this Agreement upon thirty (30)days prior written notice to the Trial Site. This Agreement may be terminated immediately at any time for any reason by the Trial Site or CRO when, in their judgment or that of the Principal Investigator, the Ethics Committee, if applicable, or the Drug Controller General of India, it is determined to be in appropriate, impractical, or inadvisable to continue, in order to protect the Study subjects' rights, welfare, and safety, or the committee otherwise disapproves the Study. If for any reason Principal Investigator becomes unavailable to direct the performance of the work under this Agreement, Trial Site shall promptly notify CRO. If the Parties are unable to identify a mutually acceptable successor, this Agreement may be terminated by either Party upon thirty (30) days written notice. Not withstanding the above a Party may, in addition to any other available remedies:
  - a) immediately terminate this Agreement upon the other Party's material failure to adhere to the protocol, except for deviation required to protect the rights, safety, and welfare of Study subjects; and/or
  - b) terminate this Agreement upon the other Party's material default or breach of this Agreement, provided that the defaulting/breaching Party fails to remedy such material default, breach, or failure to adhere to the Protocol within thirty (30) business days after written notice thereof.
- 6.5 In addition to the above, this Agreement may be terminated by Trial Site in the event of a material default or breach of this Agreement by CRO/Sponsor, or by CRO in the event of a material breach of this Agreement by Trial Site, provided that the defaulting/breaching party fails to remedy such material default or breach within thirty (30) business days after written notice thereof. In the event that this Agreement is terminated prior to completion of the Study, for any reason, Trial Site shall:
  - a) Notify the appropriate authority that the Study has been terminated;
  - b) cease enrolling subject sin the Study;
  - c) cease treating Study subjects under the protocol as directed by CRO to the extent

medically permissible and appropriate;

- d) Terminate, as soon as practicable, all other Study activities; and
- Furnish to CRO any required final report for the Study in the form reasonably acceptable to CRO.
- 6.6 Promptly following any such termination, Trial Site will provide to CRO copies of data collected pursuant to the Study protocol. Upon Sponsor's or CRO's written request, Trial Site shall provide to the requesting Party, at Sponsor's or CRO's expense, all Sponsor's Confidential Information provided under this Agreement provided, however, that Trial Site may retain such copy of Confidential Information for record keeping purposes, monitoring its obligations, and exercising its rights here under, subject to Trial Site's ongoing compliance with the confidentiality and non-use obligations set for thin this Agreement.
- 6.7 If this Study is terminated early by either Party, the Trial Site shall be reimbursed for all work completed, on a prorate basis, and reasonable costs of bringing the Study to termination incurred through the date of termination, and for non-cancellable commitments properly incurred through that date. Upon receipt of notice of termination, Trial Site will use reasonable efforts to reduce or eliminate further costs and expenses and will cooperate with CRO to provide for an orderly wind-down of the Study. In the event the prepaid any portion of payment for work pursuant to this agreement that is not actually performed as a result of termination of this agreement, the Trial Site and PI shall return such payment for such unperformed services or unexpended or cancelled fees. In the event Trial Site fails to repay such funds in a timely manner, Sponsor/CRO may deduct an equivalent amount from any payment then or later due from Sponsor/CRO to Trial Site under this or any other arrangement between the parties subject to prior intimation and detailed explanation by the Sponsor/CRO.

### 7. OWNERSHIP:

7.1 All reports, data, technical information, (including without limitation, written, printed, graphic video and audio material, any computed data base and computer data readable data form), original works of authorship and all other information generated by the Trial Site, the Principal Investigator, any other designated personnel in the course of conducting the study shall be the sole and exclusive property of Sponsor or its designee i.e. CRO, which may utilise the Data in any way it deems appropriate, subject to and in accordance with applicable laws and regulations of India and the terms of this agreement.

7.2 For the purpose of this Agreement data shall mean all data and information generated / collected by Trial Site and Principal Investigator as a result of conducting the Study in accordance with the approved protocol which may include but not limited to collection of original Study subject or patient medical records, research notebooks, source documents, or other routine internal documents. Any other data / information collected as part of routine internal documents by the Trial Site in its ordinary course of business operations shall remain the sole and exclusive property of the Trial Site. Sponsor owns and has all rights to use only the Study related Data / Information in accordance with the signed informed consent and authorization form, applicable laws, and the terms of this Agreement.

### 8. CONFIDENTIALITY:

- 8.1 All the Parties agree to treat any confidential information obtained from the other Party, or generated by the Party or its representatives as a sole and direct result of performing the services under this Agreement including, without limitation, confidential commercial, business, scientific, medical and technical information, the study drug, Protocol, Investigator Brochure, Case Report Forms, safety information, and any other data or information generated or resulting from the study recorded and available in any form or on any media (paper, disc, photos, computer systems) (hereinafter "the Confidential Information")
- 8.2 All the Parties agree not to divulge the Confidential Information to any third party or Parties, unless necessary as it relates to the performance of duties outlined in the scope of services or use said Confidential Information for any purposes other than understanding and evaluating the performance of those services. Parties further agrees to limit disclosure only to those of its officers, employees, agents, affiliates and consultants as are necessary to carry out the services in this Agreement. Parties shall take all reasonable steps to prevent the disclosure of the Confidential Information as provided herein.
- 8.3 Parties will ensure that it will incorporate similar confidentiality language (no less restrictive than this Agreement) in its written contracts with all representatives, agents, affiliates and consultants to protect Confidential Information. Any Confidential Information or intellectual property produced for performing services under this Agreement can only be used by the Sponsor/CRO for the specific Study.
- **8.4** The above provisions of confidentiality shall not apply to that part of the information which any Party is able to demonstrate by documentary evidence:
  - a. was fully in their possession prior to receipt from the other Party; or
  - b. was in the public domain at the time of receipt; or
  - becomes part of the public domain through no fault of the Party; or

- d. is lawfully received by it from a third party having a right of further disclosure; or
- e. is developed by it independent of the Information; or
- is required by law or upon a court injunction to be disclosed.
- 8.5 Trial Site and Principal Investigator may disclose the existence of this Agreement and any additional information necessary to ensure compliance with applicable, regulations, and laws in accordance with Clause 9 of this Agreement. Further data and results generated in the course of conducting the Study are Confidential Information are not allowed for publishing without prior written approval from Sponsor / CRO.
- 8.6 Parties agree that upon termination or expiration of this Agreement, at the other party's request, it shall return to the other party all Confidential Information, retaining copies of any such Confidential Information as is reasonably necessary for regulatory and insurance purposes or as it deems necessary to demonstrate the satisfaction of its obligations hereunder, all subject to the on-going obligation to maintain the confidentiality of such Confidential Information.

### 9. DISCLOSURES:

- 9.1 The confidentiality obligation shall not, however, be applied to Confidential Information, which:
  - Was, as evidenced, in the possession of the receiving Party prior to receipt of the confidential information from the other Party,
  - The Party has received from a third party without any obligation of confidentiality and which has a right to deliver such information to the other Party, or
  - c. On ground of law has to be delivered.

Any party invoking and exception set forth above has the burden of proof with respect to the existence of such an exception.

- 9.2 Each Party shall promptly return to the other Party all Confidential Information no longer needed for the purposes of this Agreement or if so requested by the other Party.
- 9.3 Should any third party, e.g. Regulatory Authority demand access to Confidential Information on grounds of law, the party shall without any delay and prior to making such a disclosure notify the other party of such a demand in writing and take prior written consent before making such disclosure. The party may then deliver only the specified Confidential Information, which the request concerns.

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### 10. PUBLICATION:

- 10.1 The Parties also understand and recognize that this Study is part of a multi-site study and that data from all sites will be pooled and analyzed, and agree that premature disclosures of data from a single site may be misleading. Sponsor /CRO, shall have the right to coordinate one or more publications of the aggregate multi-site Study results.
- 10.2 The Trial Site/Principal Investigator will report the findings of the Study to Sponsor/CRO in the form of Study reports, to be submitted to Sponsor/CRO at such stages or intervals in such forms and containing such information as set out in the protocol (including for instance the progress and the number of included patients) and/or as further agreed between the Parties.
- 10.3 The Parties acknowledge that Sponsor/CRO shall have the exclusive right to publish and present the results of the Study. Sponsor/CRO shall take into account that these results represent a joint effort among Sponsor, CRO, Trial Site and Principal Investigator. Sponsor/CRO shall mention the Principal Investigator of the Trial Site in a footnote in the manuscript as one of the participating Principal Investigators of the Study.
- 10.4 The Principal Investigator/Trial Site shall have no right to publish and present the results of the Study unless the prior written consent of Sponsor/CRO has been obtained. Sponsor/CRO recognizes the wishes of Site/PI to publish details of academic research in scientific journals. Sponsor/CRO shall however have the full right to withhold such consent.
- 10.5 Sponsor/CRO shall retain ownership of all original and completed CRFs, data, analyses and reports that result or are derived from the Study.

### 11. INVENTIONS& PATENTS:

11.1 Any invention, discovery, or improvement related to Sponsor/CRO's products or technology which is conceived or reduced to practice as a consequence of Trial Site's performance of the services hereunder (the "Inventions") shall be the sole and exclusive property of Sponsor/CRO and shall be used by Sponsor/CRO as Sponsor/CRO deems appropriate. Trial Site agrees to execute and have executed, at Sponsor/CRO's cost, assignments of the inventions to Sponsor/ CRO (including ensuring contracts between Trial Site and its representatives include appropriate assignment language to require its representatives to comply with the terms of this assignment provision and this Agreement), along with other documents that may be necessary or helpful to Sponsor / CRO in filing patent applications. or which may relate to any litigation or interference and/or controversy in connection therewith. The entire control, prosecution, and conduct of any patent application filed by Sponsor shall be outside the jurisdiction of, and without expense to, Trial Site/Principal Investigator or its Representatives. Trial Site/Principal Investigator acknowledges that

Dr. Shivani Bansal
M.D. (Medicine)

Professor
Santosh Medical College And Hospital
Ghaziabad (U.P.)
MCI-25922

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therewith. The entire control, prosecution, and conduct of any patent application filed by Sponsor shall be outside the jurisdiction of, and without expense to, Trial Site/Principal Investigator or its Representatives. Trial Site/Principal Investigator acknowledges that Sponsor / CRO has the exclusive right to file patent applications in connection with the Inventions. Trial Site /PI warrants that it will not, and will ensure (including incorporating similar language in its contracts with study sites and investigators) that its Representatives will not prevent Sponsor / CRO from filing patent applications for, or from applying the results of research carried out for Sponsor / CRO hereunder.

- 11.2 All reports, data, technical information, original works of authorship and all other information, furnished by or on behalf of Sponsor / CRO, or created specifically for Sponsor / CRO as a deliverable under this Agreement ("Work Product"), shall be the sole and exclusive property of Sponsor.
- 11.3 Notwithstanding the foregoing, Sponsor / CRO acknowledges that Trial Site /Principal Investigator possesses certain inventions, processes, know-how, trade secrets, improvements, other intellectual properties and other assets, including but not limited to analytical methods, procedures and techniques, procedure manuals, personnel data, financial information, computer technical expertise and software, which have been independently developed by Trial Site /Principal Investigator and which relate to its business or operations (collectively "Trial Site Property"). Sponsor / CRO and Trial Site /Principal Investigator agree that any Trial Site Property or improvements thereto which are used, improved, modified or developed by Sponsor / CRO under or during the term of this Agreement are the sole and exclusive property of Trial Site and Sponsor / CRO shall be liable for any misuse or unauthorized use/ dissemination of the same. In no event shall Trial Site /Principal Investigator be precluded from use of this property and its general knowledge, skills and experience, and any of its ideas, concepts, know-how and techniques used or developed by it in the course of providing services under this Agreement.

### 12. INSURANCE AND INDEMNIFICATION:

- 12.1 Trial Site shall maintain medical professional liability insurance with limits in accordance with local standards for each medical professional involved in the Study, or require that each medical professional maintain such insurance.
- 12.2 The Sponsor/CRO shall indemnify and hold harmless the Trial Site from any and all liability of trial subjects, loss, or damage it may suffer as a result of the Sponsor's negligence or breach of contract or caused by the investigational medicines, compliance with the protocol written by the Sponsor, or use of the results. Sponsor/CRO will ensure that appropriate medical insurance cover is obtained to cover the financial cost of any liabilities arising out of loss / damages occurring to trial subjects as a result of participation in the clinical trial under

the conditions specified as per the terms of this Agreement.

- 12.3 The Trial Site and Principal Investigator agrees to indemnify and hold harmless the Sponsor/CRO from any and all liability of trial subject's loss, or damage it may suffer as a result of lack of performance / negligence / harm they may suffer during their routine treatment at Trial Site which is not a part of the present study protocol and is outside the scope of this Agreement.
- 12.4 The obligation of the Sponsor hereunder shall apply only if the indemnities provides prompt notification upon receipt of notice of any claim or suit, permits the Sponsor and its attorneys and personnel to handle and control the defense of such claims or suits including pretrial, trial or settlement and the indemnitees further agrees that it will not settle or compromise any such claim or suit without the prior written consent of the Sponsor/CRO.

### 13. USE OF OTHER PARTIES' NAMES:

- 13.1 Neither the Trial Site nor CRO may use the name, trade mark, logo, symbol, or other image or trade name of the other Party or their employees and agents in any advertisement, promotion, or other form of publicity or news release or that in any way implies end or sement without the prior written consent of an authorized representative of the other Party whose name is being used. Such approval will not be unreasonably withheld.
- 13.2 Trial Site, CRO and Sponsor understand that the amount of any payment made here under may be disclosed and made public by the other party as required by lawor regulation, provided that the disclosure clearly designates the payment shaving been made to Trial Site for research and not to the physician.

#### 14. NO JOINT VENTURE ETC.:

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

# 15. MONITORING; AUDIT; REGULATORY INSPECTIONS:

- 15.1 The Principal Investigator and Trial Site shall, permit authorized personnel of the Sponsor/ CRO and any Regulatory Authority including EC to inspect the facilities of the Study site before, during and after the Study.
- 15.2 The Principal Investigator and Trial Site shall notify to the Sponsor/CRO immediately by telephone or facsimile if the Drugs Controller General-India, or any other governmental or regulatory authority requests permission to or does inspect the Principal Investigator and Trial Site's facilities or research records relating to this Study whenever and will provide in

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writing to the inspecting authority copies of all materials, correspondence, statements, forms and records which the Principal Investigator and Trial Site receives, obtains, or generates pursuant to any such study.

- 15.3 The Principal Investigator and Trial Site will permit the Sponsor/CRO to;
  - (a) Examine, inspect and audit the work performed here under and the facilities, systems and equipment at or with which the work is conducted.
  - (b) Inspect and copy all data, documents and records related to such work and the Study.

### 16. FORCE MAJEURE:

- 16.1 Any event occurring after signing the Agreement, which a party could not reasonably have taken into account at the time of the conclusion of the agreement and which prevents or delays the affected party from fulfilling of its obligations under the agreement or makes the fulfillment thereof unreasonably difficult and which cannot be overcome without unreasonable loss of time or cost, shall constitute an event of force majeure. An event of force majeure shall include: strike, war, revolt, import or export prohibition, acts of God, interruption of public traffic or distribution of energy, legal labour dispute, fire, epidemic, pandemic or any other reason having as severe and unusual effects beyond the control of the Party.
- 16.2 If a party would wish to invoke existence of an event of force majeure as a cause for the non compliance with any of its obligations under the Agreement or delay or exemption from liability, it shall without delay inform the other Party of the delay or termination of its contractual obligation in writing.

#### 17. NOTICES

- 17.1 Any notice, authorization, approval, consent or other communication will be in writing and deemed given:
  - Upon delivery in person;
  - b. Upon delivery by courier;
  - Upon delivery date by a nationally- recognized overnight delivery service such as Blue Dart/DHL etc.

Samuel Graziano Page 18 of 42

#### If to CRO:

Insignia Clinical Services Private Limited,

Attn: Mr. Amardeep Singh Designation: Director

Address: #512, Best Sky Tower, Netaji Subhash Place, Pitampura, Delhi-110034

Tel: +91-11-4904 9115

E-MAIL: clinical.operations@insigniacs.com

#### If to Trial Site:

Santosh Medical College Hospital, Ghaziabad

Attn: Dr. Alpana Agarwal

Designation: Medical Superintendent

Address: No.1, Ambedkar Road, Ghaziabad - 201 001 (U.P.)

Tel: 9811191935

E-MAIL:alpanaishi@gmail.com

# With a copy to Principal Investigator:

Attn: Dr. Shivani Bansal

Designation: Professor, Department of Internal Medicine

Address: Santosh Medical College Hospital, No.1, Ambedkar Road, Ghaziabad - 201 001

Tel: 9013451039

E-MAIL: drshivani2015@gmail.com

# 18. GOVERNING LAW:

18.1 The validity, interpretation, and performance of this Agreement shall be governed and construed in accordance with the laws of India.

#### 19. JURISDICTION:

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

# 20. ARBITRATION:

20.1 All disputes or claims whatsoever arising out of or in respect of the terms and conditions of this agreement or relating to the admissibility or liability or quantity of compensation or damages payable to or by any of the parties to this Agreement to the trial subject or his/her legal representative or the nominee shall be referred by the aggrieved party or person to the arbitration of a sole arbitrator to be appointed mutually by the Parties within a period of thirty

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(30) days of the receipt of a written request by the aggrieved. The Arbitration and conciliation Act 1996 as amended from time to time shall be applicable to such arbitration proceedings. The award of the arbitrator shall be final and binding on all the Parties thereto.

# 21. AMENDMENT:

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

# 22. ENTIRE AGREEMENT

22.1 Section and clause headings are used here in solely for convenience of reference and are not intended as substantive parts of the Parties' Agreement. This Agreement incorporate the Exhibits referenced herein. This written Agreement constitutes the entire a matter, and supersedes all other or prior agreements or understandings, whether written or oral, with respect to that subject matter except for MoU. Any changes made to the terms, conditions or amounts cited in this Agreement require the written approval of each Party's authorized representative.

IN WITNESS WHEREOF, the Parties hereto have caused this Agreement to be executed, in triplicate, by their officers, thereunto duly authorized to signify behalf of their Party.

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1. Insignia Clinical Services Pvt. Ltd

2. Santosh Medical College Hospital

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ORQ

3. Principal Investigato hiva M.D. (Medici:

Professor
Santosh Medical College And Hospital
Ghaziabad (U.P.)
Ghaziabad (U.P.)

Ghiziabad 201001 (U.P.)

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#### Exhibit-A

Insignia Clinical Services Pvt. Ltd.

ICS/LAX/2021-001 Ver. 1.0, 18 Jan. 2021

#### PROTOCOL SYNOPSIS

TITLE:

A prospective, pilot, clinical trial to evaluate the efficacy and

safety of COLchicine for improvement of clinical outcome: during COrona Virus (COVID-19) disease treatment in high-

risk INdian patients.

STUDY ACRONYM:

COLCOVEN

PROTOCOL NUMBER: ICS/LAX/2021-001

NUMBER OF SUBJECTS Total of \$4 subjects (42 per group) to be screened / enrolled TO BE ENROLLED AND in 1:1 ratio in either of the two study treatment arms to

achieve statically powered minimum sample.

CLINICAL PHASE:

RANDOMIZED:

Phase-II Clinical Trial.

INDICATION:

Coronavirus (COVID-19) Disease.

STUDY OBJECTIVES:

#### Primary Objective:

· To evaluate the efficacy of Colchicine for improvement of overall clinical outcomes in high risk patients infected with coronavarus (COVID-19).

#### Secondary Objective

 To evaluate the safety and tolerability of Colchicine when used for improvement of overall clinical outcomes in high risk patients infected with coronavirus (COVID-

#### STUDY DURATION:

Total duration of participation for all subjects, who participate in the study will be for a maximum period of 45 days, from the time of beginning of treatment. The total duration of treatment in test and reference groups may vary, however, the daily doing of Colchicine in Test group may continue up to 28 days from the day of first dose. Based on the Principal

#### CONFIDENTIAL

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investigator discretion, the study medication may be stopped curing the study.

#### STUDY DESIGN AND METHODOLOGY:

This is a Pilot Phase II, randomized, open label, prospective, comparative, two-arm, multi-center clinical study to evaluate the efficiety and safety of Colchicine for improvement of overall clinical outcomes when added to Standard of Care (SOC) treatment in high-risk Indian patients suffering with coronavirus (COVID-19) disease.

The proposed study is a two phase clinical study wherein first phase is Treatment Phase of 18 days followed by Follow-up Phase of 14 days. High risk panents with clinically confirmed & documented diagnosis of moderate coronavirus disease (COVID-19) as per MOH Criteria who require hospitalization for management of the disease, i.e.,

- Confirmed diagnosis of COVID-19 demonstrated by positivity in RT-PCR 2019nCov test on respiratory tract (masopharyngeal) or opharyngeal) specimens.
- Presence of clinical features of dyspnea and/or hypoxia, fever, cough, including SpO1 = 94% (range 90-94%) on room air. Respiratory Rate > 24 and < 30 breaths per minute.</li>
- Age above 40 to 65 years (both inclusive)
- Having at least one of the high-risk criteria, i.e., obstity (BMI = 30 kgmn²), diabeted mellitus, uncontrolled hypertension (diastolic blood pressure = 90 mm Hg & syntolic blood pressure =150 mm Hg), known respiratory disease (including authma or chronic obstructive pulmonary disease), known heart failure, known coronary disease.

will be screened and errolled for participation in the study as per study protectl.

The treatment period with investigational product in test group will be 28 days from the day of first dote. It is however necessary that all patients in either test or council groups be allowed to take concomitant SOC as per the prescribed schedule for entire duration of the study, as applicable.

During entire duration of participation in the study, all patients in both test and/or control groups will take SOC as advised per individual treatment plan and will be asked to monitor signs & symptoms of disease, status of clinical recovery and adverse events, if any.

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During the both phases of study, climical evaluations shall be performed as per the below mentioned schedule:

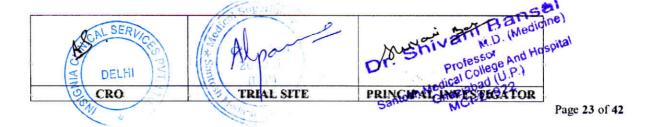
- Screening Period (Day -2 to Day 0)
- Randomization (Day 1\*)
- Treatment Period (Day 2 to Day 28)
- End of Treatment ("Next day of last treatment dose" Or Day 29)
- Follow-up Period [Day 42 ± 2, i.e. 14 ± 2 days (2 weeks) from EOT\*\* or "Death" whichever is earlier]
- \*Day 1 to be coincidered from the day when the first dose of study medication as pertreatment plan is administrated to the patient.
- \*\* Based on the treating physician's opinion, patient's clinical status & outcome of disease treatment, hospital discharge time points may vary for specific patient. Discharge from hospital will depend on clinical status of patient and signs & symptoms of the disease, according to standard clinical practice. Patients who demonstrate improvement in disease status and do not show signs of respiratory distress, breathlessness and hypoxia (SpO2 > 93% on room air) and not requiring auxiliary oxygen may qualify for discharge based on clinical judgement of the investigator. Hospital discharge will be independent of the treatment schedule for investigational product.

The study flow-chart for the proposed study is as below:



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At acreening, all subjects will undergo following study assessments:

- · Demographics.
- · Personal history.
- Complete medical and surgical history.
- Vital signs (heart rate, blood pressure, body temperature, respiratory rate, oxygen saturation).
- · Physical examination.
- Concomitant medications.
- Laboratory Investigations to be done at Screening shall include:
  - : CBC (including RBC, Hematocrit (HCT, packed cell volume, PCV). Hemoglobin, Platelet, Mean platelet volume, Differential & Absolute Leukocyte Count)
  - : Biochemistry (LFT, RFT, CRP, D-Dimer, Sr. Fernan)
  - c Urinalysis (physical, microscopic & chemical examination)
  - Inflammatory markers [hs-cTnI, NT-ProBNP, Neutrophil-Lymphocyte (N/L) ratio, IL-6, TNF-a]
- Urine pregnancy test (only for females of child bearing potential).
- · ECG (12-lead)
- Chest X-Ray / CT-Scan (based on PI Discretion if required to assess pneumonia)
- 2D-Echocardiography
- A positive nasopharyngeal / oropharyngeal swab test for COVID-19 nucleic acid test to be done using RT-PCR technique (if not performed already within 72 hours prior to screening).
- Any additional tests / screening procedures which are not part of above study
  assessments, however, may be required as per standard clinical practice for
  management of COVID-19 patients or in line with national COVID-19
  management protocol are allowed for study participants, however, details of all
  such investigations should be captured in respective patient CRF.

After screening, all patients who will qualify for participation in the study as per inclusion exclusion criteria will be randomized in a 1:1 ratio in either of the two study groups.

Note: If screening and randomization are on same day, then assessments of screening

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will be considered for baseline. All laboratory investigations and X-Ray performed within 72 hours prior to study envolment can be considered for baseline values).

During randomization (Day 1), all eligible enrolled patients in test group will receive Colchicine loading dose (1mg followed by 0.5mg after 3 hours) on Day 1 & 0.5mg BID from Day 2 up to Day 28 plus Standard of Care (SOC) whereas patients in control group shall receive only Standard of Care (SOC).

During the hospitalization and for entire duration of the study, patients will be monitored to assess chinical signs and symptoms of the disease, laboratory tests values (brochemical & hematology) and adverse events as required per standard clinical practice.

SOC to be given will be decided by the investigator based on the clinical condition of the patients and should be in line with per the Clinical Management Protocol for COVID-19 patients prescribed by Government of India. Details of SOC and supportive care will be recorded for each patient in their respective Case Report Form (CRF) on daily basis for the entire duration of hospitalization. Upon discharge, patients will be given diary cards to record the time of intake of study medications which may be prescribed to them for usage during remain duration of study.

To ensure consistency in line of treatment being administered for all patients who will participate in the study, different institutions/study sites/investigator's participating will be advised / encouraged to refer the updated / latest Clinical Management Protocol for COVID-19 prescribed Government of India while choosing SOC for patients.

Clinical assessments during the study shall be performed as per following schedule:

# Treatment Phase (Day 2 to Day 28):

- Vital signs, physical examination, adverse events, concomitant medication and clinical signs & symptoms of disease (body temperature, respiratory rate, oxygen saturation, respiratory examination) of the subject will be monitored on the daily basis during hospitalization.
- Routine laboratory investigations as per national COVID-19 management protocol are allowed during the study.
- Nacopharyngeal / Oropharyngeal swab for COVID-19 nucleus acid test (RT-PCR)

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to be repeated at Discharge (in cases of -ve report not achieved already).

As per Investigator's opinion, if there is need to change the line of treatment for any patient due to safety issues, such patient shall be withcrawn from the study and managed as per investigator's clinical judgement. In case there is a 2-point deterioration in clinical status of the patient during the treatment, such patients will be immediately withdrawn from the study and shall be treated as per investigator's judgement and shall be considered as treatment failures. In cases of early withdrawals due to any reasons, all possible attempts shall be made by the investigator to complete laboratory investigations, clinical safety and efficacy assessments specified for EOT time point.

Discharge from hospital may occur anytime depending on investigator judgement and clinical recovery status of individual patient according to stundard clinical practice. Upon discharge from hospital, patients will be advised to monitor the overall health and status of clinical recovery and adverse events, if any. In case of Discharge before ECT, patients will continue treatment & mandatory investigations at per the prescribed schedule, however, investigational product will not be administered beyond Day 28 to patients who will participate in test group

#### Follow-up Phase (Day 29 to Day 42 ± 2 days):

Follow Phase will begin from EOT, i.e. Day 29 and will be independent of hospital discharge. Follow-up Phase shall continue for next  $14\pm2$  days for each patient during which each patient required to visit study site at the end of study and earlier in case of deterioration in signs & symptoms of disease and / or adverte events (if any). During follow-up user following study related clinical investigations / assessments may be performed based on clinical judgement of the investigators

- Vital signs, physical examination, adverse events, concountant medication and chaical signs & symptoms of disease (body temperature, respiratory rate, oxygen saturation, respiratory examination) of the subject will be monitored on the daily till discharge.
- . ECG (12-lead) to be repeated at follow-up visit.
- Routize laboratory investigations which are required as per routine clinical gractice.

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- If at any time during the follow-up period, the investigator performs any laboratory test / chircal investigation as per his/her chircal judgment the data & reasons for such testing should be promptly recorded in the patient CRF.
- Adverse events (senous, non-serious, expected, not expected, related) will be monitored throughout the complete study period. All serious adverse events will be reported within 24 hours of occurrence to DCGI. Ethic: Committee and Sponsor (vijay, dhondge@laxai.com and pvg@insigniacs.com).

The primary outcome measure for this study will be:

 Time to clinical improvement of 2-points on WHO 8-point ordinal scale [Time frame: 28 days from residentization]

Secondary outcome measures for this study will include:

- Improvement in cardiac & biochemical inflammatory marker: [ns-cIn(I), D-dimer, NT-ProBNP, CRP, Neuropeil-Lymphocyte(N/L)ratio, Sr. Ferritin, IL-6, INF-a]
- . Time to discharge from hospital
- Rate of viral clearance
- Patients requiring auxiliary axygen therapy inon-invasive/measive/ & time on auxiliary axygen therapy.

Other outcome measures for this study will be:

- All-cause mortality.
- Adverse events (Serious, Expected/Unexpected, Related Non-Related).

Safety and tolerability to study medication will be evaluated based on laboratory tests (bematology and biochemistry). ECG (12-lead), routine clinical examinations, and the incidence, reventy and type of AEs reported by the patient: over the course of treatment and entire study duration. All AEs (Senous Non-Senious, Expected Not expected Related/Nor Related) reported during the study will be roded using the Medical Dictionary for Regulatory Activities (MedDRA updated with COVID-19 terms) and grouped by treatment.

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Clinical efficacy and safety data will be collected everyday till discharge from hospital & during the follow-up phase as per safety & efficacy assessment schedule.

#### DIAGNOSIS TARGET POPULATION AND KEY INCLUSION CRITERIA:

Male and female subjects between 40 to 65 years (both inclusive) with clinically confirmed and documented diagnosis of moderate coronavirus disease (COVID-19) confirmed by positivity in RT-PCR 2019-nCov test on respiratory tract (nasopharyngeal) oropharyngeal) specimens and presenting clinical features of dyspnea and/or hypoxia, fever, cough, including SpO2 < 94% (range 90-94%) on room air, Respiratory Rate > 24 and < 30 breaths per minute.

All qualified subjects should have at least one of the high-rick criteria, i.e. obesity (BMI  $\ge 30 \text{ kg/m}^2$ ), diabetes mellitus, uncontrolled hypertension (diantolic blood pressure  $\ge 90 \text{ mm}$  Hg & systolic blood pressure  $\ge 150 \text{ mm}$  Hg), known respiratory disease (including atthma or chronic obstructive pulmonary disease), known heart failure, known coronary disease OR should demonstrate signs of cardiac injury due to Elevated troponin level at the time of screening / study entry.

All patients who present above symptoms and are able to provide voluntary informed consent by self and/or legally accepted representative (LAR) will be screened for participation in the study and will be enrolled for treatment and randomized in either treatment groups (Test vs. Control) in a 1.1 rano.

Other inclusion and exclusion criteria for the study shall be as follows:

#### Inclusion Criteria:

- Male & Female patients with age ranging from 40 to 65 years (both inclusive)& female (non-pregnant, non-lactating, post-menopausal, surgically sterilized or practicing 3 reliable method of birth control during the duration of study)
- Clinically stable condition for at least 6 months before enrollment.
- Confirmed diagnosis of at least moderate COVID-19 symptoms demonstrated by:
  - a. Positivity in RT-PCR 2019-nCow test on respiratory tract (nasopharyngeal / oropharyngeal) specimens.

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- b Presence of clinical features of dyspnea and/or hypoxia, fever, cough, including SpO2 = 94% (range 90-94%) on room air, Respiratory Rate = 24 and = 30 breaths per minute.
- 4 Significant COVID-19 symptoms, and judged by the treating doctor to be at high risk of progression to severe category due to presence of any of the following:
  - a Having at least one of the high-risk criteria, i.e., obesity (BMI ≥ 30 kg/m²), diabetes mellitus, uncontrolled hypertension (diastolic blood pressure ≥ 90 mm. Hg systolic blood pressure ≥150 mm. Hg), known respiratory disease (including authma or chronic obstructive pulmonary disease), known heart failure, known coronary disease;
  - b. Demonstrating tigms of cardiac injury due to Elevated troponin level.
- 5 Patients who require hospitalization for control of disease at the time of study entry.
- 6 Within 7 days from symptom conset or within 72 hours of laboratory diagnosis of SARS-CoV2.
- 7 Able to take oral tablets and agreeing not to pasticipate in any other study for duration of participation in this study.
- 8 Willing to sign voluntary informed consent for participation in the study and willing to adhere to all protocol procedures. In case the subject is unable to provide informed consent than the same should be obtained from legally acceptable representative (LAR).

#### Exclusion Criteria

- History of present alress: (will be based on treating physician's opinion)
  - a. Neurological and neuro-developmental disorders.
  - b. Congenital heart disease
  - c. Severe heart disease or a history of clinically significant airhythmia: which may affect participants' safety (According to the ECG or medical history). Corrected QT interval of 450 millisecond: or higher (according to the Bazett formula) or a 12-lead surface ECG. Abnormal ECG (to eliminate concerns that a potential interaction between colchicins and hydroxychloroquine could lead to excess QT prolongation.)

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- Requirement of oxygen supplementation SL massi cannols at the time of enrollment.
- Treating physician's clinical judgement that the patient will require mechanical respiratory support within 24 hours.
- Patient currently in Septic shock or with hemodynamic instability requiring vasopiessors.
- 5. History of chrhosis.
- A subject undergoing hemodialytis.
- 7. Severe gastrointestinal failure, severe gastrointestinal disorders, or stomach ulcer.
- 5 Patient it currently taking colchicine for other indications (gour or Familial Mediterranean Fever).
- Patien: with inflammatory bowel disease (Crohn's disease of therative colifis), chronic diarrhea or malabiorytion;
- 10. Seven Hepatic Insufficiency (ALT or AST > 5 times ULN) or Renal Failure (eGFR using the MDRD equation for all subjects = 30 mL/m).
- Patient received Reinderivin, Sarifumab, Tooffizamas Lopinava / Ritonava or other immunomodulator given for COVID-19 treatment prior to study entry.
- 12. Patien. is on (and cannot discontinue) a strong CYP3A4 inhibitor (e.g. clarithromycin, indinavir, maconazole, ketoconazole, nefrizodone, nelfinavir, ritonavir, saquinavir, telifhromycin, mazanavir), a moderate CYP3A4 inhibitor (e.g. diltiazem, verspannil, flueonazole, amprenovir, apropitant, fosemprenavir) er a P-gp Inhibitor (e.g. cyclosporine, ranolazine).
- 13. Patients who may require IL 6 inhibitors as per clinical judgment of the investigator for management of inflammation at the time of study entry.

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14 Pregnant or lactating women; women of a childbearing age with a positive pregnancy test

#### INVESTIGATIONAL MEDICINAL PRODUCT (IMP):

Test Group: Colchicine loading dote (lmg followed by 0.5mg after 3 hours) on Day 1 & 0.5mg BID from Day 2 up to Day 28 + SOC

Control Group: Standard of Care (SOC)

#### Notest

- SOC will be administered as per Principal Investigator discretion in line with national COVID-19 clinical management protocol. Standard of Care (SOC) may include licensed antivurals, oxygen inhalation, oral or intravenous rehydration, electrolyte correction, antipyretics, analgesics, anti-inflammatory and antiemetic drugs.
- In cases where there is significant increase in oxygen requirement and/or inflammatory markers are increasing, even after 48 hours of admission into the study, investigator is allowed to use either 6 mg of dexamethasone (IV or Oral) OR 40 mg of prednisone OR 32 mg of methylprednisolone for management of inflammation.
- Details of all such concomitant medications, usage will be captured and specific patient CRF for subset analysis at the end of study.

#### DISPENSING OF IMP:

IMP will be handled by a pharmacist or designated personnel at the site.

Patients who are randomized in the study will be instructed to take the study drug as per the protocol. Patients will be informed during the consent process that if they are selected in test group they will receive Colchicine for a period of maximum 28 days upon randomization and will be followed up for additional 14 days (2 weeks) for signs &

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symptoms of climical recovery.

The test product will be supplied by the Sponsor for dispensing to the patient during the study treatment phase. The Investigator should confirm the receipt of the study drugs in writing, including follow-up supplies. The investigator / designated personnel will be responsible for dispensing / re-dispensing of study medication and collection of used / empty packs as per patient allocation & randomization schedule. Only patients enrolled in the test group will receive the IMP.

Sponsor representative/designee will ensure at their interim visits that all unused carrons / packs are intact and not opened. Investigator designee will file opened treatment allocation carron pack in subject file as documented evidence and accordingly dispense during the study period. Designated study team member at site will have to dispense the treatment to the subject and prior to dispensing the treatment will have to record the randomization number appearing on the treatment allocation envelope and the visit code prior to dispensing it.

The storage and handling instructions for Colchicine oral tablets will be mentioned on the label carton. Store at Room Temperature. Keep out of the reach and sight of children. Do not use after the expiry date. Investigator Pharmacist will be advised to store the study drugs in a cool place, protected from heat, freeze and direct sunlight. Reconciliation between the amount of medication supplied, dispensed and returned to sponsor must be performed and any discrepancies accounted for should be documented with a reason for the same.

Compliance will be checked by the count of used and unused study drug returned. Study drug accountability log will be maintained by the investigator or the authorized personnel. Any discrepancies should be well documented in the source notes as well as in the case report form.

#### DOSE AND MODE OF ADMINISTRATION:

Test products is for oral use only.

Subject: will be randomized to either of the two treatment groups:

Test Group:

Colchicine

loading dose (lmg

+ Standard of Care

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followed by 0.5mgafter 3 hours) on Day 1 & 0.5mg B.D from Day 2 up to Day 18

Control Group:

Standard of Care

#### CLINICAL ENDPOINTS:

#### EVALUATION OF SAFETY:

An adverte event is defined as any untoward medical occurrence (sign, symptom or laboratory finding), regardless of severity and whether or not attributed to the investigational product.

All adverse events, whether observed by an Investigator or Study Coordinator or reported by the subject, whether related to study drug or not related to study drug, shall be documented on the CRF and subject records, together with details, i.e. date of onset, the duration and inventity of each episode, the action taken, the relationship to the investigational product and the degree of seventy, the sentousness and the outcome.

Safety and tolerability to treatment were evaluated according to routine laboratory tests (haematology and biochemistry), 12-lead ECGs, clinical examinations, and the incidence, severity and type of AEs reported by the patients over the course of treatment.

All AEs were coded using the Medical Dictionary for Regulatory Activities (MedDRA updated with COVID-19 terms) and grouped by treatment. The number and percentage of AEs, SAEs AEs leading to discontinuation, and AEs related to study drug will be summarized by system organ class, preferred term and treatment group. The number and percentage of AEs by severity will also be summarized. All AEs will be displayed in listings. No inferential analyses are planned.

Summary of wirl signs, laboratory parameter values at relevant time points at well at change from baseline will be presented. Summary of physical examination findings will be presented by visit Summary of concomitant medications will be presented.

Safety evaluations in the study will be performed using Safety Analysis Set (SAF). The Safety Analysis Set (SAF) concerts of all subjects who took at least 1 dote of study

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medication, and will be used for safety analysis.

A descriptive analysis comparing the rate, intensity and severity of adverse events in both the measurem groups will be performed

#### EVALUATION OF EFFICACY:

The primary outcome measure for this study will be:

Time to clinical improvement of 2-points on WHO 3-point ordinal scale
[Time frame: 18 days from randonization]

Secondary outcome measures for this study will include:

- Improvement in cardiac & biachenical inflammatory markets
  [its-cTr(I) D-dimer, NT-Pro3NP, CRP, Neutrophil-Lymphocyte(N/L)ratio, Sr.
  Ferritin, IL-6, INF-a]
- Time to discharge from hespital
- Rate of viral clearance
- Patients requiring auxiliary exygen therapy (non-invasive/invasive) & time on auxiliary exygen therapy.
- · All-cause martality

The efficacy evaluations will be performed using the following analysis sets for this study:

- Full Analysis Set (FAS): The Full Analysis set will consist of all subjects who
  were randomized, received at least 1 dose of investigational product and had at
  least 1 post baseline measurement. This will be the primary analysis set for
  efficacy analysis.
- Modified latent-to-treat population (mITT): This ITT population will consist of all enrolled subjects who met inclusion/exclusion criteria and are on study medication and have at least one post baseline efficacy assessment.

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Per protocol population (PP): The Per-Protocol set will be a subset of subjects in
the FAS set who complete the study without any important protocol deviations.
The enteria to determine protocol deviations will be defined in the SAP. The PP
set will be a secondary analysis set for efficacy analyses.

This will constitute of all the enrolled subjects who were compliant with the assigned study treatment and completed evaluation as per protocol with no protocol deviations that would affect the evaluation or interpretation of the primary efficacy endpoint. Protocol compliance will be evaluated by questioning the subjects, reviewing subject diaries for missed doses etc. Subjects will be considered protocol compliant if he/she used at least 75% but no more than 125% of study drug doses, based on the subject study medication records.

#### STATISTICAL METHODS:

Validated CFR compliant statistical software will be used for analysis in this study. A statistical analysis plan (SAP) will be prepared separately from this protocol which gives descriptions of the statistical methods, models, hypothesis, and analysis populations to be analyzed. The SAP will serve as a companion to the protocol and will serve as the de facto documentation of the proposed statistical evaluations.

#### SAMPLE SIZE ESTIMATION:

The proposed study is being conducted to evaluate the efficacy of Colchicine when given alongside Standard of Care (SOC) Vs. SOC for the treatment of coronavirus disease (COVID-19). The primary endpoint for the study was time to improvement/response. Thus, the point of clinical improvement or response was treated as an event.

Based on the existing literature data on the current standard of case vertus a historical standard of case, the hazard ratio for time to recovery was found to be 1.8. The sample size was calculated with level of significance for two-sided alpha assumed at 5% and power of 80%.

A total sample size of 62 was obtained. Patients will be randomized to the treatment and the standard of care group in a 1:1 ratio with 42 participants in each group. Assuming a dropout rate of around 35%, the total sample size will be 84. Therefore, for this study a total of eighty-four (84) patients may be enrolled (42 patients in each Arm 1 and Arm2) to achieve a sample size of 62 (31 per group) completed patients for this pilot study.

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# EXHIBIT-B PART 1- BUDGET & PAYMENT SCHEDULE

Protocol Title: A prospective, pilot, clinical trial to evaluate the efficacy and safety of <u>COL</u>chicine for improvement of clinical outcomes during <u>CO</u>rona<u>Virus</u> (COVID-19) disease treatment in high-risk <u>IN</u>dian patients. [Acronym: COLCOVIN Study]

Protocol Number: ICS/LAX/2021-001

Estimated Per Subject Fee [including all fixed costs, institutional overheads (as applicable) & other Compensation below]:

- PI Clinical Investigation Charges (Screening, Treatment till Discharge, EOT & Followup Visit) = INR 20,000/- Per Completed Subject at the Trial Site\*
- Cardiologist Clinical Investigation Charges (Screening, Discharge & EOT) = INR 3,000/- Per Completed Subject at the Trial Site\*
- Hospital Charges (Bed + Oxygen) = INR 36.000/- Per Completed Subject at Trial Site\*
- Mandatory Study Investigations (details as per Table 1) = INR 10,000/- Per Completed Subject at the Trial Site\*

#### Table 1:

S.No.	Investigation	Repetition Frequency as per protocol			
1.	ECG	All days during hospitalization till Discharge.			
	Ì	End of Treatment Visit (EOT)			
		Follow-up Visit			
2.	2D-ECHO	Screening, Discharge & End of Treatment	4.1111		
3.	RT-PCR	Screening, Discharge & End of Treatment			
4.	Chest X-Ray	creening, Discharge & End of Treatment			

Optional Lab. Investigation Charges as per PI direction (rates prescribed in Table 2):

#### Table 2:

Investigation	Cost	Investigation	Cost	Investigation	Cost
CBC (including absolute and differential blood count)	180/-	D-Dimer	685/-	NT-proBNP	1500/-
Liver Function Test	450/=	Sr. Ferritin	340/=	IL-6	1350/-
Renal Function Test	486/-	Urine Analysis	100/-	TNF-α	2200/-
C-Reactive Protein	210/-	Urine Pregnancy Test	100/-	hs-cTn(I)	1012/-



<u>Subject Stipends</u>: The subject stipend is intended to offset the Study subject's costs associated with travel expenses and meals, where appropriate, incurred as a result of Study participation, and shall be reflected in the informed Consent Form, as will be provided to the Study subject.

<u>Screen Failure Payments</u>: No screen failure payment will be provided either to investigators or to study site a result of participation in the present study.

#### **Payment Terms:**

- a) This Exhibit-B is for completed records for valid subjects. A valid subject is defined as a subject who meets eligibility requirements to enroll in the Study and does not have significant Protocol violations that would exclude his/her Data from analysis. Sponsor/CRO anticipates closure of enrollment upon randomization of a total of 84 valid subjects across all the sites participating in the study. In the event 84 total valid subjects are enrolled, further recruitment will be suspended. No payment will be made for any subject excluded from analysis because of Protocol violations within the Study personnel's control.
- b) Trial Site acknowledges this is a multicenter Study designed to evaluate a set number of Study subjects. When enrollment of the target number of Study subjects in the Study is complete, those sites will be notified and instructed not to continue enrolling Study subjects.
- c) Sponsor/CRO will provide, through a third party vendor, thermometer equipment (as required) valued at up to Rs. 4,000 for use as called for in the Protocol upon termination of the Study at Trial Site, the equipment will be returned in accordance with Sponsor/CRO's or designee's instructions.
- d) Equipment Calibration: Trial Site shall be responsible for ensuring Trial Site-owned equipment utilized by Trial Site in accordance with this Agreement is serviced and/or calibrated as per manufacturer's recommendation and/or more frequently as required by Sponsor/CRO. Records verifying the equipment calibration and maintenance shall be provided to Sponsor/CRO upon request for calibrations which are performed solely at the request of Sponsor/CRO, and that are not part of the recommended scheduled maintenance suggested by manufacturer, Sponsor/CRO will reimburse Trial Site for the actual cost without mark-up for each calibration processing of payment will begin upon receipt of invoice and supporting documentation in accordance with paragraph e) below.
- e) To be eligible for payments, the procedures must be performed in full compliance with the Protocol and this Agreement, and data submitted must be complete, correct and entered into the CRF in accordance with Sponsor/CRO's instructions. Payments will be made, at a minimum, on a fortnightly basis, once the corrected invoices are received. These payments will include milestone payments, as well as all invoiced and approved costs from the prior payment cycle. Ongoing reconciliations will be performed during the course of the study. Any erroneous payments discovered will be applied to any pending or future payments due. No payments will be made until all erroneous payments have been offset. If no pending or

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future payments exist, Trial Site will promptly refund overpayment according to Sponsor/CRO's instructions.

Original invoices pertaining to this study should be submitted for reimbursement to the following address:

TO

Insignia Clinical Services Pvt. Ltd. Unit No. 512, 5th Floor, Best Sky Tower, NetajiSubhash Place, Pitampura, New Delhi-110034.

A copy of the invoice, together with the supporting documentation should be emailed to cral@insigniacs.com and failure to do so, might delay the payment process

Please note that invoices must contain the following information, or they will be returned, delaying payment:

- Trial Site name
- Principal Investigator name
- Protocol number
- Invoice number and date
- Date & description of services provided Supporting documentation (i.e. third-party invoices, receipts)
- Any claims for reimbursement of adverse events must be submitted in a separateInvoice
- Site Purchase Order (PO) number
- ICS GST Number 07AADCI0529A1Z7
- PAN (permanent account number)
- Site (micro, small and medium enterprises) MSME number (If applicable) Site GST number (if applicable)
- HSN/SAC (Harmonized System of Nomenclature/ Service Account Code)
- f) Costs from, and reimbursement for, activities and items not specifically referenced above, including, but not limited to staff costs, laboratory fees, x-rays, scales and questionnaires (quality of life, etc.), data coordinator fees, travel fees, and subject reimbursement other than any subject stipends specifically identified above, are incorporated into the per-subject payment above. No additional reimbursement for these costs is otherwise provided.
- g) For the avoidance of doubt, the Principal Investigator and/or the Trial Site are responsible for providing any and all compensation benefits and/or insurance to the investigational staff. It is also understood and expressly acknowledged that the investigator and the investigational staff are not eligible to participate in, nor are they eligible for coverage under any of the

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- Sponsor/CRO's benefit plans, programs, employment policies, procedures or workers compensation insurance.
- h) The Parties agree this Exhibit-B is part of the Agreement and clarifies the payment schedule associated with this Agreement. Payments shall be made in accordance with the provisions set forth in this Exhibit-B, with the last payment being made after the site completes all of its obligations under the Agreement and any exhibits thereto. The Principal Investigator acknowledges and agrees his or her judgment with respect to his or her advice to and care of each subject is not affected by the compensation the site receives hereunder. The parties agree the payce designated below is the proper payce for this Agreement and payments under this Agreement will be made only to the following payce.

Payee Name:	SANTOSH TRUST
(This should be a business name and should	
match the business name used to file for your	
tax EIN or other tax ID number)	
Tax ID number:	PAN No: AAIT56921N
(Tax ID number must exactly match the payee	GST No:
Name indicated above)	
Contact Information:	Name:
(Name, Phone No., & e-mail address)	s
	Phone No:
	E-mail:
Payee Address:	No.1, Ambedkar Road, Ghaziabad - 201
	001 (U.P.)

Trial Site will have 30 days from the last subject out (LSO) date of the Study to resolve the payment discrepancies, which have arisen during the course of study.

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# **PART-2 TAXES**

- 1. Notwithstanding anything contained in the Agreement, the Trial Site agrees that it is eligible to receive part of the consideration being the Goods and Services Tax(GST) charged in respect of the supply only after the details of such supply are uploaded by the Trial Site in the Form GSTR-1 (or such other form as may be notified in lieu thereof from time to time), which is subsequently reflected in Form GSTR-ZA (or such other form as may be notified in lieu thereof from time to time), made available electronically to the Sponsor/CRO, and are considered as matched with the corresponding details furnished by the Sponsor/CRO in its returns in terms of the relevant provisions of the GST Laws.
- 2. The Trial Site agrees to indemnify the Sponsor/CRO and keep it indemnified from and against reasonable tax liabilities that may accrue or be demanded by a Taxing Authority, in respect of or in connection with the execution of scope of work or payments made due to the Trial Site, arising under the said Agreement or anything done pursuant to the same. Any such compensation towards liabilities by the Trial Site to the Sponsor/CRO will be made within ninety (90) days of the liabilities accruing / demanded raised by Tax Authorities on the Sponsor/CRO either by way of issuance of demand or show cause notice or order or decree.
- The Trial Site undertakes to be compliant with the anti-profiteering provision under Section 171 of the Central Goods and Services Tax Act, 2017.

#### 4. Other terms:

- a. The consideration payable under this Agreement shall be exclusive of applicable Goods and Services Tax (GST) including but not limited to CGST and SGST /UTGST or IGST, and or applicable cess, as the case may be.
- b. The Trial Site shall periodically pay its tax liabilities in compliance with me GST Laws in connection with the goods/ services supplied under this Agreement such that me Sponsor/CRO is entitled to claim such credit of input tax with respect to the good/services supplied under this Agreement as permitted under the GST Laws.
- c. The Trial Site hereby undertakes that it will make timely payments of all taxes, duties, levies imposed by Government (including but not limited to GST), be responsible for filing of all necessary tax returns and undertake all necessary compliances in accordance with applicable statutory requirements under the relevant statute in relation to sum received from the Sponsor/CRO.
- d. The Trial Site hereby undertakes that it will issue the tax invoices within the statutory time limits as prescribed under the GST laws and in the manner and with

- all the prescribed particulars as are required to be specified as per the GST Laws.
- e. The Trial Site hereby undertakes that the address / location of the CRO to which the invoice will be issued by the Trial Site will be as per the address mentioned in the Purchase Order (PO) issued by the CRO. Separately, prior to issue of an invoice, the Trial Site shall intimate the CRO about the address / location of the CRO to which the invoice will be issued and a prior approval from the CRO in this respect will be taken by the Trial Site.
- f. The Trial Site undertakes that a debit note/ supplementary invoice/credit note with appropriate references to the original invoice will be issued only in such circumstances as agreed between the parties.
- g. Post supply of goods / services under this Agreement, the Trial Site shall cooperate with the CRO and provide any information that may be reasonably requested by the CRO in connection with claiming such credit of input tax under the GST Laws such as tax invoice or debit note issued by the Trial Site or such other taxpaying document(s) as may be required as proof of payment of applicable GST by the Trial Site.
- h. Where, transactions in respect of which the CRO has claimed input tax credit are notified as unmatched vis-à-vis the corresponding disclosures made by the Trial Site in his periodic returns, the Trial Site would extend necessary assistance including inter alia carrying out revision/ rectification of its returns, to enable the CRO to retain such claimed credits.
- i. The Trial Site undertakes that it has secured required GST Registration(s), which is/are in full force and effect and no action or claim is pending nor threatened to revoke or terminate such registration(s) or declare such registration(s) as invalid.

#### **EXHIBIT-C**

# (WITHOUT PREJUDICE)

#### STATEMENT ISSUED BY TRIAL SITE

- That the Dr. Shivani Bansal is one of the employee of the Trial Site and has signed an Agreement or equivalent document to this effect.
- The P1 is obligated to assign to the Trial Site all inventions and discoveries made in the course of their Consultancy arrangement, explicitly mentioned in the Agreement signed by both the Parties.
- Trial Site approves and agrees Principal Investigator to be the investigator for the study and responsible to the conduct of the study.

For Santosh Medical College Hospital

Dr. AlpanaAgrawal (Medical Superintendent)

Date and Stamp

Dr. Shivani Bansal (Principal Investigator)

CRO

Signature

Date and Stamp

2015/2021

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RINCIPAL INVESTI

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TRIAL SITE



CIN NO: U85100DL2012PTC243279 GST NO: 07AADCI0529A1Z7

#### TO WHOM IT MAY CONCERN

This is to certify that we Insignia Clinical Services Pvt. Ltd. hold MOU dated 19 Oct. 2020 with Santosh Deemed to be University, Ghaziabad for conduct of human clinical trials at their facility, i.e, Santosh Medical College & Hospital, Ghaziabad.

In accordance with the aforesaid MOU, we are performing clinical trials of different therapeutic indications at Santosh Medical College & Hospital, Ghaziabad. The honorarium for clinical trial payments for the above studies are being made to research account of Santosh Deemed to be University, Ghaziabad as per the invoices / clinical trial agreements.

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S.No	Protocol No.	Study Title	Principal Investigator	Site	Final Invoice Amount in lakhs	Final Invoice Amount (PI Grant)	Site	PI	Site	PI	Site	PI
1	ICS/SYN /2021- 001	A phase iii, multicentric, randomized, double blind, parallel group, comparative, clinical study to evaluate the efficacy and safety of bilastine tablets 40 mg for the treatemnt of chronic spontaneous urticaria.	Dr. V K Garg	Santosh Deemed to be University	1.469			(50% of	e payment h the patient o College, Sa	consultation	and Site (	Santosh
2	ICS/LAX /2020- 006	"A multicentric, phase ii, randomized, open label clinical study to evaluate efficacy, safety and tolerability	Dr. Ashok Kumar	Santosh Deemed to be University	2.4525	41,250	66,217 (30%) 2 May 2022	11,138 (30%) 2 May 2022	30% after completi on of CRF and	30% after completi on of CRF and	40% after Closeout	40% after Closeout

		of niclosamide for the treatment of hospitalized corona virus disease (covid- 19) patients							resolutio n of queries	resolutio n of queries		
3	ICS/LAX /2021- 001	A prospective, pilot, clinical trial to evaluate the efficacy and safety of colchicine for improvement of clinical outcomes during coronavirus (covid-19) disease treatment in high-risk indian patients".	Dr. Shivani Bansal	Santosh Deemed to be University	4.09157	70,000	1,10,472 06 Jun 2022	18,900 06 jun 2022	30% after completi on of CRF and resolutio n of queries	30% after completi on of CRF and resolutio n of queries	40% after Closeout	40% after Closeout
4	ICS/LAB /2021- 004	An observational, Prescriber based, Multicentric, Post Marketing surveillance study (PMS) to generate safety & efficacy data of fixed dose combination (FDC) of codeine phosphate 10mg & Chlorphenramine Maleate 4mg per 5 ml Oral Syrup for management of Symptoms of Dry Cough in Adult Patients	Dr. Ashok Kumar	Santosh Deemed to be University	2.782	250,000	1,25,190 (50%) 19 April 2022	112500 (50%) 29 April 2022	50 % on closeout	50% on closeout	NA	NA
5	BITEL/ WBL/P3/ 2021	A Multicenter, Randomized, Double- Blind, Parallel-Group, Comparative, Active- Controlled, Phase III Clinical Trial to evaluate the Efficacy	Dr. Ashok Kumar	Santosh Deemed to be University	2.16	805,330	2,50,000 19 Mar 2023	1,36,000 19 Mar 2023	50 % on closeout	50% on closeout	NA	NA

and Safety of Fixed-					
Dose Combination of					
Bisoprolol 5 mg and					
Telmisartan 40 mg					
tablet versus Fixed-					
Dose Combination of					
Metoprolol Succinate					
ER 50 mg and					
Telmisartan 40mg in					
subjects with mild to					
moderate hypertension.					

# Thank You

Kartik Sahni Digitally signed by Kartik Sahni Date: 2023.04.17

Kartik Sahni 15:04:32 +05'30'

Associate Director

Corp.Off: 512 , Best Sky Tower , Netaji Subhash Palace , Pitampura - 110034 © 011 - 49049115 , 09868679414 Regd. Off.: B-19 , Vandana Apartments , Sector - 13 , Rohini , Delhi - 110085 URL : www.insigniacs.com

22/04/2022

Single Arm Study

No

**PMS** Drug



CTRI/2021/10/037217 [Registered on: 08/10/2021] - Trial Registered Prospectively

# Clinical Trial Details (PDF Generation Date :- Tue, 28 Mar 2023 10:26:35 GMT)

**CTRI Number Last Modified On Post Graduate Thesis** 

Type of Trial Type of Study

**Study Design Public Title of Study** 

Scientific Title of Study

Chlorpheniramine maleate for management of symptoms of dry cough in adult patients. AN OBSERVATIONAL, PRESCRIBER BASED, MULTICENTRIC, POST MARKETING SURVEILLANCE STUDY (PMS) TO GENERATE SAFETY & EFFICACY DATA OF FIXED DOSE COMBINATION (FDC) OF CODEINE PHOSPHATE 10mg & CHLORPHENIRAMINE MALEATE 4mg PER 5ml ORAL SYRUP FOR MANAGEMENT OF SYMPTOMS OF DRY COUGH IN ADULT PATIENTS.

A post marketing surveillance study to monitor the safety and efficacy of Codeine phosphate and

Secondary IDs if Any

Secondary ID	Identifier
ICS/LAB/2021-004 Version 2.0 Date 19 OCT 2021	Protocol Number

**Details of Principal** Investigator or overall **Trial Coordinator** (multi-center study)

-						
Details of Principal Investigator						
Name	Dr R M Chhabra					
Designation	Medical Monitor/Trial Coordinator					
Affiliation	Insignia Clinical Services Pvt. Ltd.					
Address	Insignia Clinical Services Pvt. Ltd., Room # 512, Clincal Trial Division, Clinical Operations Department, Best Sky Tower, Netaji Subhash Place, Pitampura North West, DELHI 110034, India. Insignia Clinical Services Pvt. Ltd. Room # 512, Clincal Trial Division, Clinical Operations Department, Best Sky Tower, Netaji Subhash Place, Pitampura North West, DELHI 110034, India. North West DELHI 110034 India					
Phone	011-49049115					
Fax	011-49049115					
Email	Chhabradrrm@gmail.com					

**Details Contact** Person (Scientific Query)

Details Contact Person (Scientific Query)						
Dr R M Chhabra						
Medical Monitor/Trial Coordinator						
Insignia Clinical Services Pvt. Ltd.						
Insignia Clinical Services Pvt. Ltd. Room # 512, Clincal Trial Division, Clinical Operations Department, Best Sky Tower, Netaji Subhash Place, Pitampura North West, DELHI 110034, India. Insignia Clinical Services Pvt. Ltd. Room # 512, Clincal Trial Division, Clinical Operations Department, Best Sky Tower, Netaji Subhash Place, Pitampura North West, DELHI 110034, India. North West DELHI 110034 India						
011-49049115						
011-49049115						
Chhabradrrm@gmail.com						



# **Details Contact** Person (Public Query)

	Details Contact Person (Public Query)							
Name	Dr R M Chhabra							
Designation	Medical Monitor/Trial Coordinator							
Affiliation	Insignia Clinical Services Pvt. Ltd.							
Address	Insignia Clinical Services Pvt. Ltd. Room # 512, Clincal Trial Division, Clinical Operations Department, Best Sky Tower, Netaji Subhash Place, Pitampura North West, DELHI 110034, India. Insignia Clinical Services Pvt. Ltd. Room # 512, Clincal Trial Division, Clinical Operations Department, Best Sky Tower, Netaji Subhash Place, Pitampura North West, DELHI 110034, India.  North West DELHI 110034 India							
Phone	011-49049115							
Fax	011-49049115							
Email	Chhabradrrm@gmail.com							

CTRI Website URL - http://ctri.nic.in

Source of Monetary or **Material Support** 

**Source of Monetary or Material Support** > LABORATE Pharmaceuticals India Limited, E-11 Industrial Area Panipat 132103 Haryana

# **Primary Sponsor**

Primary Sponsor Details					
Name LABORATE Pharmaceuticals India Limited					
Address E-11 Industrial Area Panipat 132103 Haryana					
Type of Sponsor	Pharmaceutical industry-Indian				

**Details of Secondary Sponsor** 

Name Address LABORATE Pharmaceuticals India Limited E-11 Industrial Area Panipat 132103 Haryana

**Countries of** Recruitment

**List of Countries** India

# Sites of Study

maa								
Name of Principal Investigator	Name of Site	Site Address	Phone/Fax/Email					
Dr A Gopal Rao	Government Medical College and Government General Hospital (Old RIMSGGH)	Research Wing 2nd Floor Department of Medicine, Government Medical College and Government General Hospital (Old RIMSGGH), Srikakulam, Andhra Pradesh- 532001 Srikakulam ANDHRA PRADESH	9912320517 muralidhargudla@yaho o.com					
Dr Ram Babu	Jaipur Golden Hospital	Room NO. 04, Clinical Trial Division, Medicine Dept., 02, Institutional Area, Sector III, Rohini, Delhi 110085 North West DELHI	011-27907000 011-27907000 JGHDSMO@GMAIL.C OM					
Dr Pathak Niranjan Pandurang	PCMCs PGI Yashwantrao Chavan Memorial Hospital	2nd Floor General Medicine Department PCMCs PGI Yashwantrao Chavan Memorial Hospital Sant Tukaram Nagar Pimpri Pune 411018	7057582759 drpratiksunservices@g mail.com					



		Pune MAHARASHTRA	
Dr Ashok Kumar	Santosh Medical College & Hospital	3rd Floor, Clinical Trial Division, No 1, Ambedkar Road, Ghaziabad 201001 Ghaziabad UTTAR PRADESH	1204666650 smchgzb@gmail.com

#### Details of Ethics Committee

		1	
Name of Committee	Approval Status	Date of Approval	Is Independent Ethics Committee?
Institutional Ethics Committee Govt. Medical College Govt. General Hospital	Approved	31/01/2022	No
Institutional Ethics Com mittee-Yashwantrao Chavan Memorial Hospital	Approved	05/01/2022	No
Society for Academic Scientific Translational Research Advancement Ethics Committee	Approved	25/11/2021	Yes
Society for Academic Scientific Translational Research Advancement Ethics Committee	Approved	25/11/2021	Yes

Regulatory Clearance Status from DCGI

Health Condition / Problems Studied

Intervention / Comparator Agent

Status	Date	
Not Applicable	No Date Specified	

Health Type	Condition
Patients	Other specified respiratory disorders

Туре	Name	Details
Intervention	Chlorpheniramine Maleate 4mg	Codeine Phosphate 10mg and Chlorpheniramine Maleate 4mg per 5 ml syrup two times daily for 7 days
Comparator Agent	NOT APPLICABLE	NOT APPLICABLE

# Inclusion Criteria

Comparator Agent	INOT ALL LICABLE	INOT ALL LICABLE		
Inclusion Criteria				
Age From	18.00 Year(s)			
Age To	65.00 Year(s)			
Gender	Both			
Details	surgically sterilized surgically sterilized from 18 to 65 years (both incleough (less than 7 days) of a symptoms as Throat Pain, the (Fever if before recruitment. drug (which will affect the stull Investigational Product for the during the study period (exceworsens as per br/> study physical product for the during the study period (exceworsens as per study physical product for the during the study period (exceworsens as per study physical physical product for the during the study period (exceworsens as per study physical phy	ant, non-lactating, post-menopausal, racticing a reliable method of birth study) study) study) Subjects with age ranging lusive). your origin and may be with related roat redness, Throat irritation/itching, note of bronchial mucus/phlegmer any antibacterial or antiviral treatment ubjects ready to abstain from using any dy outcome) other than treatment of the study condition you in cases when patient's condition hysician. In this case, Study physician otic, if your of any herbal or ayurvedic treatment		



or<br/>br/> gargles directed to ease coughing or throat parameters.<br/>6. Willing to provide written informed consent<br/>br/> 7. Willing and able to understand and comply with all study requirements

#### **Exclusion Criteria**

	Exclusion Criteria
Details	Subjects with known allergy or hypersensitivity to Codeine     Phosphate or
	Chlorpheniramine Maleate or any of its components.
	Subjects who had taken any medicated confectionary, throat
	pastille, spray or any
	product with demulcent properties, any cough medicines or drugs
	containing
	antihistamines within last 24 hours prior to screening.
	3. Subjects taking medications with known cough promoting side effects (e.g.,
	angiotensin converting enzyme inhibitors or angiotensin II receptor blockers) that
	in the opinion of the investigator are causing symptoms of cough.
	4. Subjects with diagnosis of diseases of pneumonia, asthma, sinusitis, allergic
	rhinitis, as well as heart disease.
	5. Severe cough requiring hospitalization
	6. Subjects who had used any local anesthetic within the past 24 hours.
	7. Subjects who have used a longer acting or slow release analgesic during the
	previous 24 hours.
	8. Maintenance therapy with any drug, or history of drug
	dependency, alcohol abuse,
	or serious neurological or psychological disease
	9. Any other condition, which in the opinion of the
	clinician/investigator, could
	interfere significantly with the treatment and assessment process
	10. Use of any investigational therapy within 30 days prior to
	randomization

Method of Generating Random Sequence Method of

Concealment

Blinding/Masking

**Primary Outcome** 

Not Applicable

Not Applicable

Not Applicable

Outcome	Timepoints
Adverse Events, Serious Adverse Events, Unexpected Adverse Events, Adverse Drug Reactions and Treatment Emergent Adverse Events.	7 Days

# **Secondary Outcome**

Outcome	Timepoints
Change in the cough severity( daily) and frequency (daily) score assessed during follow-up visit at Day 3 and Day 7 or up to complete recovery (whichever is earlier) compared to the baseline.	Day 3 and Day 7
Number of awakenings in the night due to cough (24 hours) assessed during follow-up visit	Day 7
Time taken for complete cough relief (days) assessed during follow-up visit	Day 7
Change in score of throat pain and throat irritation	Day 7



#### **Target Sample Size**

Total Sample Size=200

Sample Size from India=200

Final Enrollment numbers achieved (Total)=0 Final Enrollment numbers achieved (India)=200

**Phase of Trial** 

Date of First Enrollment (India)

Date of First
Enrollment (Global)

**Estimated Duration of Trial** 

Recruitment Status of Trial (Global)

Recruitment Status of Trial (India)

Publication Details Brief Summary Post Marketing Surveillance

15/10/2021

No Date Specified

Years=0 Months=6 Days=0

Not Applicable

Completed

Not Applicable

This is a prospective, single arm, multi-center, open-label, prescriber based, observational Post Market Surveillance study in Indian adult subjects who have symptoms of cough associated with upper respiratory allergies or common cold aged 18 years or older. The current study will aim to evaluate the safety and efficacy of fixed dose combination of Codeine Phosphate 10mg & Chlorpheniramine Maleate 4mg per 5ml oral syrup in the actual field conditions for the management of symptoms of cough associated with upper respiratory allergies or common cold.

The duration of individual participation will be approximately 7 days (7 days treatment period).

Key safety assessments include : Adverse Events (AEs), Serious Adverse Events (SAEs), Unexpected Adverse Events, Adverse Drug Reactions.

Key efficacy assessments include: Change in the cough severity (daily) and frequency (daily) score assessed during follow-up visit at Day 3 and Day 7 or up to complete recovery (whichever is earlier) compared to the baseline, Number of awakenings in the night due to cough (24 hours) assessed during follow-up visit, Time taken for complete cough relief (days) assessed during follow-up visit, Change in score of throat pain and throat irritation.

# INSIGNIA CLINICAL SERVICES PVT LTD (from 1-Apr-22) SANTOSH HOSPITAL( ASHOK KUMAR)

Ledger Account

# 1-Apr-22 to 4-Mar-24

						Page 1
Date	Particulars		Vch Type	Vch No.	Debit	Credit
1-Apr-22 D	r Opening Balance					2,62,125.00
19-Apr-22	Cr STATE BANK OF INDIA		Payment	74	1,25,190.00	
21-Apr-22	Cr STATE BANK OF INDIA		Payment	82	1,12,500.00	
	Dr STATE BANK OF INDIA		Receipt	7		1,12,500.00
29-Apr-22	Cr STATE BANK OF INDIA		Payment	107	1,12,500.00	
2-May-22	Cr STATE BANK OF INDIA		Payment	139	11,138.00	
3-Feb-23	PAYMENT MADE AGAINST INVOIC RS 37125  Dr (as per details) Ec Fees (Hypertension)		Journal	431		1,94,400.00
	TDS PAYABLE U/S 94J 01001 TO 01082	21,600.00 Cr				
19-Mar-23	Cr STATE BANK OF INDIA		Payment	1410	1,36,080.00	
					4,97,408.00	5,69,025.00
С	r Closing Balance				71,617.00	
					5,69,025.00	5,69,025.00



# INDIAN MEDICAL ASSOCIATION

(Registered under Societies Act XX1 of 1860)

GHAZIABAD CHAPTER (2022-23)

IMA BHAWAN-SECTOR-8, Raj Nagar, Ghaziabad, 201001 (U. P.)

Mob. No. 9999081239, 9555650853, Email: ghaziabadima@gmail.com, Web: www.imagzb.com

PRESIDENT DR. SUNDEEP VARSHNEY 9810148852 PRESIDENT ELECT DR. VANI PURI RAWAT

VICE PRESIDENT DR. RAJIV GOEL (ENT) 9810181251 JT. SECRETARY DR. PREETY TYAGI

HONY. SECRETARY DR. GYANENDRA S. MITTAL 9899100517 JT. SECRETARY DR. NEHA PODDAR

TREASURER DR. BHAVUK MITTAL 9540191068 JT. TREASURER DR. V. K. BATRA

Date: 6th Jan 2022

Patron CMO Ghaziahad

IMA HQs/U P State Dr Rajeev Goel (Surg.)

Dr V B lindal Ex. Officio

Dr R K Garg Dr Sanjeev K Jain

Dr Tarun Aggarwal (Anes.) **Advisory Board** Dr Naresh Chand

Dr R K Poddar Dr Ashok Agarwal Dr Subhash Agarwal

Dr H L Sharma Dr Shalabh Gupta Dr D.P. Singh Dr Ashish Agarwal

Scientific Team Dr Shashi Arora Dr Amitabh Goel Dr Ashish Prakash

Dr Arun Kumar (Pead.) Dr Rajiv Garg Dr Amit Jain Dr Puneet Gupta Dr Nikunj Jain

Press & Media Incharge Dr Navneet Verma Crisis Management

Dr Sushil Tyagi Or Anii Rathi Dr Pradeep Goel Dr A K Anuragi Dr Anil Tomar Dr Apoorva Agrawal

Web Master Dr Sanjay Jain Dr Bharat Rastogi IMA BCT Dr Alit Dinkar Dr Arvind Govil

School Awareness & School Health (Mission Pink Health -1)

Dr Neelu Khaneia Dr Madhu Poddar Dr Reena Gupta Dr Aruna Agarwal Dr Alona Kansal Dr Archana Sharma

Dr Prahlad Chawla Dr Pramod Sabharwal Cancer Awareness

(Mission Pink Health -2) Dr Madhu Gupta (SN) Dr Rashi Agarwal Dr Archana Verma Dr Reenu Goel Dr Neetu Masand Dr Sundeep Agarwal

IMA - HBI

Dr Santosh Ch Agarwal Dr Sangeeta Garg **IMA Excursion** 

Dr Rajeev Aggarwal (Pead.)

Dr Abhinay Goel Dr Vipin Agarwal Sports Team Dr Urnesh Madan Dr Kuldeep Gogia Dr Subhash Goel Dr Pallav K Rastogi

Dr Satish Tyagi Dr Ekta Dr Ritu Jain Health & Yora

Dr Mukesh Agarwal Dr Smita Agrawal Dr Shalini Agrawal

News & Views Dr Manisha Gupta Dr Parul Singhal Dr Nalinee Garg IMA Shakti & WDW

Dr Seema Varshney Dr Rashmi Sharma Dr Sarla Mehta

**Cultural Team** Dr Atul Gunta Dr Mohan Bandhu Gupta

Dr H H D Bhardwaj Dr Mukta Agarwal Dr Vinita Mittal Dr Sarita Anand Dr Aink Sharma

Catering Dr Apoory Goel Dr Harshit Kansal

Area Executives Dr Rajeev Tyagi Dr Sachin Agarwal (Ex Tre.)

Dr Dhruv Sharma Dr Prachi Pal Dr Achal Swami

Dr Manisha Jain Agarwal Dr Shweta Mishra Dr Raiesh Kalra Dr Rajeev Goel (Path)

Dr Vikas Sharma **Dr Sumit Gupta** 

To,

Dr Shalabh Gupta

**HOD of General Surgery** 

Santosh Medical College and Hospital

Ghaziabad

Dear Shalabh Gupta.

We are pleased to inform you that upon thorough review of your project titled as below:

Title	Department	Principal Investigator	Amount
Use of Cautery in Surgical Incisions	General Surgery	Dr Shalabh Gupta	1,00,000

Cautery Pencils for skins Incisions worth Rs. 1,00,000/- will be provided to Santosh Medical College & Hospital, Ghaziabad.

Kindly share the final report of the project once it is complete.

Best Regards

Dr Sundeep Varshney President IMA

2022-23

or. Sundeep Varshne M.B.B.S., M.D MCI NO. 7843 L-216, Laipal Nagar, Sahibabad MGI No. 7843 Ghexished (U.P.)

> TOGETHER WE CAN DO GREAT THINGS LONG LIVE IMA GHAZIABAD

Permanent Invitees

All Past Presidents

President & Secretary of Sub Specialties



# INDIAN MEDICAL ASSOCIATION

(Registered under Societies Act XX1 of 1860) GHAZIABAD CHAPTER (2021-22)

IMA BHAWAN-SECTOR-8, Raj Nagar, Ghaziabad, 201001 (U. P.)

Mob. No. 9999081239, 9555650853, Email: ghaziabadima@gmail.com, Web: www.imagzb.com

PRESIDENT DR. R. K. GARG 9891515215 PRESIDENT FI

9891515215 PRESIDENT ELECT DR. SUNDEEP VARSHNEY VICE PRESIDENT DR. ABHINAV GOEL 9810177667 JT. SECRETARY DR. ALPNA KANSAL

HONY. SECRETARY DR. SANJEEV KR. JAIN 9811006993 JT. SECRETARY DR. PRACHI PAL TREASURER DR. TARUN KUMAR 9810390115 JT. TREASURER DR. V. K. BATRA

Date: 6th Dec 2021

Patron

CMO Ghaziabad IMA HQs/U P State

Dr Sharad Kr Agarwal Dr Rajeev Goel (Surg.) Dr Rajiv Goel (ENT) Ex. Officio

Dr Ashish Kr Agarwal Dr Vani Puri Rawat Advisory Board

Dr Arun Gupta (Ortho) Dr R K Poddar Dr Ashok Gupta Dr Ashok Agarwal

Dr H L Sharma
Scientific Team
Dr Naresh Chand
Dr Shashi Arora
Dr Vinjeta Diwakar

Dr Vinieta Diwakar Dr Ashish Prakash Dr Ashish Prakash Dr Puneet Gupta Dr Amitabh Goel Dr Anurag Singhal Dr Amit Jain

Dr Nikunj Jain Press & Media Incharge Dr Navneet Verma

Crisis Management Dr Sushil Tyagi

Dr Arun Kumar (Pedia) Dr Anil Rathi Dr Harish Sharma

Dr Harish Sharma Dr A K Anuragi Web Master Dr Sanjay Jain IMA BCT Dr Navin Kumar

Dr Arvind Govil Dr Atul Jindal School & Public Health

Dr Madhu Gupta (SN) Dr Subhash Agarwal Dr Prahlad Chawla Dr Rajiv Garg

Dr Sarika Jain Dr Neetu Masand Dr Malvika Gupta Social Awareness Dr Madhu Singhal

Dr Madhu Singhal Dr Neelu Khaneja Dr Madhu Poddar

Dr Reena Gupta Dr Archana Sharma Dr Aruna Agarwal Dr Rashi Agarwal

Dr Rashi Agarwal IMA Shakti Dr Vinita Mittal

Dr Sarita Anand Cultural Team Dr Atul Gupta

Dr Mohan Bandhu Gupta Dr HHD Bhardwai

Permanent Invitees
All Past Presidents

President & Secretary of Sub Specialties

IMA - HBI

Dr Santosh Ch Agarwal Dr Shalabh Gupta Dr V B Jindal Go Green

Go Green
Dr Rakesh Bansal
IMA Excursion
Dr D P Singh
Dr Alok Sharma

Dr Alok Sharma Sports Team Dr Kuldeep Gogia Dr Umesh Madan Dr Apoorva Agrawal

Dr Ritu Jain
Dr Pallav K Rastogi
Dr Sarika Kesarwani
New Member
Coordinator
Dr Sharad Gupta

Dr Apporv Goel Health & Yoga Dr Shalini Agrawal Dr Smita Agarwal Dr Seema Varshney

News & Views
Dr Rajeev Agrawal (Ortho)
Dr Dhirendra Singh

Dr Dhirendra Singh
Dr Seema Gupta
Dr Parul Singhal
Catering
Dr Pradeep Goel

Dr Reenu Goel

Area Executives
Dr Subhash Goel
Dr Mukesh Grover
Dr Rajeev Aggarwal (Pedia)

Dr Rajeev Goel (Path) Dr Achal Swami Dr Vikas Sharma Dr Manisha Jain Dr Anup Mittal Dr Shishir Srivastava

Dr Pankaj Gupta Dr Naveen Agarwal (Skin) Dr Saurabh Agarwal (Ortho)

Dr Rajeev Tyagi Dr Gaurav Sirohi Dr Sachin Agarwal (Ex Tre.)

Dr Dhruy Sharma

Dr R K Garg

To,

Dr Shalabh Gupta

Professor and Head

Department of General Surgery

Santosh Medical College and Hospital

Ghaziabad.

Dear Dr Shalabh Gupta,

We are pleased to inform you that upon thorough review of your project titled as below:

Title	Department	Principal Investigator	Amount
Role of Uroflowmetry     In Urinary outflow     Disorders	General Surgery	Dr Shalabh Gupta	1,20,000

Gadgets worth Rs. 1, 20,000/- will be provided to support the above project

Kindly share the final report of the project once it is complete.

Best Regards

Dr R K Garg President IMA 2021-22



TOGETHER WE WILL MAKE A HEALTHY WORLD"

LONG LIVE IMA GHAZIABAD

Date: 28/07/2021

To,

Dr. Jyoti Batra

Dean Research

Santosh Deemed to be University

Subject: Request for research funding

Respected Mam,

We have received a request from your side for a research grant to conduct medical/dental research in various departments. We have received your proposals and revert back after review committee's decision.

S.No.	Title	Name of Principal investigator
1	A Study on Profile of Poisoning Cases in a Tertiary Care Hospital in Ghaziabad	Dr Shilpa Singh
2	Uncoupling proteins in various gene-environment interaction associated with heavy metal exposure and type 2 Diabetes Mellitus in North Indian Population	Dr Juhi Aggarwal, Dr Jyoti Batra

Rajeev Khanna (Authorized Signatory)

Date: 13/01/2022

To,

Dr. Jyoti Batra

Dean Research

Santosh Deemed to be University

Subject: Approval for research funding

#### Respected Mam,

I am pleased to inform you after thorough discussion with you and your faculty members, I am ready to fund the following research projects worth a sum of INR 60,000.

S.No.	Title	Name of Principal investiga tor	Amount (INR in Lakhs)	Study duration
1	A Study on Profile of Poisoning Cases in a Tertiary Care Hospital in Ghaziabad		0.30	6 Months
2	Uncoupling proteins in various gene- environment interaction associated with heavy metal exposure and type 2 Diabetes Mellitus in North Indian Population	Dr Juhi Aggarwal, Dr Jyoti Batra	0.30	3 Months

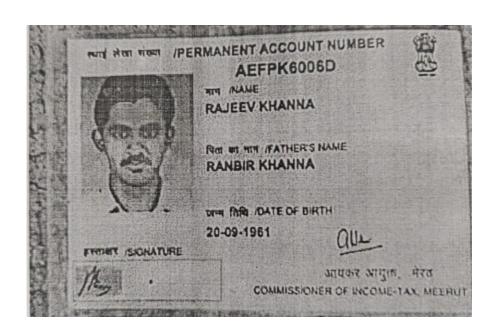
Please share with me the full proposals within 30 days of receiving this letter. Further, please submit a copy of final project report post completion.

Thank you and regards.

Rajeev Khanna (Authorized Signatory)

CC to:

- 1. Dr Shilpa Singh
- 2. Dr Juhi Aggarwal, Dr Jyoti Batra







### Clinical Trial Details (PDF Generation Date :- Tue, 28 Mar 2023 10:29:03 GMT)

**CTRI Number Last Modified On Post Graduate Thesis** 

No

Type of Trial Type of Study

**Study Design** 

Scientific Title of

Study

**Public Title of Study** 

Secondary IDs if Any

**Details of Principal** Investigator or overall **Trial Coordinator** 

(multi-center study)

CTRI/2022/01/039787 [Registered on: 28/01/2022] - Trial Registered Prospectively

30/09/2022

Interventional

Drug Randomized, Parallel Group, Active Controlled Trial

A Clinical Trial to evaluate the efficacy and safety of Bisoprolol and Telmisartan Fixed Dose Combination Tablets for management of Hypertension.

A Multicenter, Randomized, Double-Blind, Parallel-Group, Comparative, Active-Controlled, Phase III Clinical Trial to evaluate the Efficacy and Safety of Fixed-Dose Combination of Bisoprolol 5 mg and Telmisartan 40 mg tablet versus Fixed-Dose Combination of Metoprolol Succinate ER 50 mg and Telmisartan 40mg in subjects with mild to moderate hypertension.

Secondary ID	Identifier
BITEL/WBL/P3/2021 version 2.0 date 14.10.2021	Protocol Number
14.10.2021	

Details of Principal Investigator			
Name	Dr R M Chhabra		
Designation	Trial Coordinator		
Affiliation Insignia Clinical Services Pvt. Ltd.			
Address	Insignia Clinical Services Pvt. Ltd. Room # 512, Clinical Trial Division, Clinical Operations Department, Best Sky Tower, Netaji Subhash Place, Pitampura North West, DELHI 110034, India North West DELHI 110034 India		
<b>Phone</b> 011-49049115			
Fax 011-49049115			
Email Chhabradrrm@gmail.com			

**Details Contact** Person (Scientific Query)

Details Contact Person (Scientific Query)				
Name Dr R M Chhabra				
<b>Designation</b> Trial Coordinator				
Affiliation Insignia Clinical Services Pvt. Ltd.				
Address  Insignia Clinical Services Pvt. Ltd. Room # 512,Clinical Tria Clinical Operations Department, Best Sky Tower, Netaji Su Place, Pitampura North West, DELHI 110034, India North West DELHI 110034 India				
<b>Phone</b> 011-49049115				
Fax 011-49049115				
Email Chhabradrrm@gmail.com				

**Details Contact** Person (Public Query)

	Details Contact Person (Public Query)		
Name Dr R M Chhabra		Dr R M Chhabra	
<b>Designation</b> Trial Coordinator		Trial Coordinator	
Affiliation Insignia Clinical Services Pvt. Ltd.		Insignia Clinical Services Pvt. Ltd.	
		Insignia Clinical Services Pvt. Ltd. Room # 512, Clinical Trial Division, Clinical Operations Department, Best Sky Tower, Netaji Subhash	





	Place, Pitampura North West, DELHI 110034, India North West DELHI 110034 India
Phone	011-49049115
Fax	011-49049115
Email	Chhabradrrm@gmail.com

#### Source of Monetary or **Material Support**

Source of Monetary or Material Support
> Windlas Biotech Limited 40/1, Mohabewala Industrial Area, Dehradun – 248 110 Uttarakhand,
India

#### **Primary Sponsor**

Primary Sponsor Details		
Name Windlas Biotech Limited		
Address 40/1, Mohabewala Industrial Area, Dehradun – 248 110 Utta India		
Type of Sponsor Pharmaceutical industry-Indian		

#### **Details of Secondary Sponsor**

Name	Address	
Windlas Biotech Limited	40/1, Mohabewala Industrial Area, Dehradun –	
	248 110 Uttarakhand, India	

#### **Countries of** Recruitment

Dr A Gopal Rao

#### Sites of Study

List of Countries				
India				
Name of Principal Investigator	Name of Site	Site Address	Phone/Fax/Email	
Dr Sudhir Kumar Bhatnagar	Abhinav Multispeciality Hospital	Room No 01 Department of Cardiology, Abhinav Multispeciality Hospital, Nayanakasha, Kamal	9823148978 a_bawangade@yahoo. com	

Chowk, Nagpur, Maharashtra 440017

MAHARASHTRA

Dept. of Medicine,

9912320517

Nagpur

Govt. Medical College



		Bypass, Kasba, Kolkata Kolkata WEST BENGAL	
Dr Bal Kishan Gupta	S P Medical College and AG Hospitals	Department of Medicine S P Medical College and A G Hospitals Bikaner Rajasthan 334001 Bikaner RAJASTHAN	7615914143 manojbkn108@gmail.c om
Dr Laxmi Kant Goyal	S.M.S. Medical College and Attached Hospitals	Ground Floor, Department of Medicine S.M.S. Medical College and Attached Hospitals JLN Marg Jaipur Rajasthan- 302004 Jaipur RAJASTHAN	09462651019 drlkgoyal@gmail.com
Dr Ashok Kumar	Santosh Medical College & Hospital	3rd Floor, Clinical Trial Division, No 1, Ambedkar Road, Ghaziabad 201001 Ghaziabad UTTAR PRADESH Ghaziabad UTTAR PRADESH	1204666650 smchgzb@gmail.com
Dr R M Chhabra	Saroj Super Speciality Hospital	Department of Internal Medicine, Saroj Super Speciality Hospital, Bhagawan Mahavir Marg, Near Madhuban Chowk, Block A, Sector 14, Rohini 110085 New Delhi DELHI	9147903333 drchhabrarm@yahoo.c o.in
Dr Suhas N Kalashetti	Shree Samarth Hospital	Room No. 12 Department of Clinical Research Shree Samarth Hospital 227, Karande Chowk Pune, 411011 Pune MAHARASHTRA	02026128345 skalashetti@yahoo.com

#### Details of Ethics Committee

		100 (10 (0) 11110 (	
Name of Committee	Approval Status	Date of Approval	Is Independent Ethics Committee?
Ethics Committee S.M.S. Medical College and Attached Hospitals	Approved	27/04/2022	No
Ethics Committee, SP Medical College	Approved	25/02/2022	No
Institutional Ethics Committee Government Medical College and Government General Hospital	Approved	31/01/2022	No
Institutional Ethics Committee Ruby General Hospital	Approved	28/03/2022	No





PDF of Trial
CTRI Website URL - http://ctri.nic.in

Institutional Ethics Committee Shree Samarth Hospital	Approved	16/04/2022	No
Jasleen Hospital Ethics Committee	Approved	21/02/2022	No
Rajalakshmi Hospital Institutional Ethics Committee	Approved	15/03/2022	No
Society for Academic Scientific Translational Research Advancement Ethics Committee	Approved	18/01/2022	Yes
Society for Academic Scientific Translational Research Advancement Ethics Committee	Approved	08/02/2022	Yes

## Regulatory Clearance Status from DCGI

Status	Date
Approved/Obtained	15/11/2021

#### **Health Condition / Problems Studied**

#### **Health Type** Condition Patients Essential (primary) hypertension

Intervention / **Comparator Agent** 

Туре	Name	Details
Intervention	Fixed-Dose Combination of Bisoprolol 5 mg and Telmisartan 40 mg tablet	One tablet daily for 84 days
Comparator Agent	Fixed-Dose Combination of Metoprolol Succinate ER 50 mg and Telmisartan 40 mg tablet	One tablet daily for 84 days

#### **Inclusion Criteria**

Inclusion Criteria			
Age From	18.00 Year(s)		
Age To	65.00 Year(s)		
Gender	Both		
Details	\ \ \ \ \ \ \ \ \ \ \ \ \ \ \ \ \ \ \		

#### **Exclusion Criteria**

Exclusion Criteria			
Details	1. Subjects previously sensitive to any of the ingredients of the fixed-dose combination under study or beta-blockers or angiotensin receptor blockers, 2. Subjects with clinically significant renal (estimated glomerular filtration rate: 114 mm Hg) 5. Subjects with evidence of any cardiac arrhythmia on ECG 6. Any known cardiac disease/disorder in which any of the study medication is contra-indicated (e.g. severe bradycardia, heart block greater than a first degree or significant first-degree block, cardiogenic shock, decompensated cardiac failure, sick sinus syndrome without pacemaker etc.) 7. Subjects with known significant		



respiratory/liver/kidney/neurological diseases / uncontrolled diabetes,
8. Pregnant and lactating women or the women of child bearing age
who are not practising the effective means of contraception,

- 9. Subjects otherwise judged to be inappropriate for inclusion in the study by the investigator's judgment
- 10. Subjects who will receive some other drug during the study besides that in the protocol that could alter the pharmacokinetic/ pharmacodynamic profile of the study drug,
- 11. Subjects with known alcohol or drug abuse
- 12. Subjects with known history of HIV, Hepatitis B and Hepatitis C

#### **Method of Generating Random Sequence**

Method of

Concealment Blinding/Masking **Primary Outcome**  Computer generated randomization

Pre-numbered or coded identical Containers

Participant and Investigator Blinded

Outcome	Timepoints
Percentage of the subjects achieved the target	12 weeks
levels of clinical BP among mild to moderate	
hypertensive subjects (target level: SBP less	
than 140 mm Hg and DBP less than 90 mm Hg)	

#### **Secondary Outcome**

Outcome	Timepoints
Mean reduction in systolic and diastolic blood pressure measured in sitting position compared to baseline	4, 8 and 12 weeks
Proportion of responders after 12 weeks of dosing (Responder rate defined as the proportion of subjects with a decrease in diastolic BP by at least 10 mmHg).	12 weeks
Reduction in mean heart rate compared to baseline	4, 8 and 12 weeks
Adverse Events assessment, Physical and systemic examination, Vital signs, Lab abnormalities	4, 8 and 12 weeks

#### **Target Sample Size**

Total Sample Size=264

Sample Size from India=264

Final Enrollment numbers achieved (Total)=292 Final Enrollment numbers achieved (India)=292

**Phase of Trial** 

**Date of First** 

**Enrollment (India)** 

**Date of First** 

**Enrollment (Global)** 

**Estimated Duration of** 

Trial

Phase 3

29/01/2022

Years=0

No Date Specified

**Recruitment Status of** 

Months=9 Days=0

Trial (Global) **Recruitment Status of** 

Trial (India)

**Publication Details** 

**Brief Summary** 

Not Applicable

Completed

NIL

In India, Bisoprolol and Telmisartan are already approved and marketed. Therefore, considering

unmet need for an FDC and based on regulatory requirement M/s. Windlas Biotech Ltd. proposes

present study be conducted to generate data on the Indian population. The study design is a multi-ce ntre study to evaluate efficacy and safety of fixed-dose combination (FDC) of Bisoprolol 5 mg and



Telmisartan 40 mg tablet in subjects with mild to moderate hypertension. The purpose of the presen study is to demonstrate that a fixed-dose combination (FDC) of Bisoprolol tablet and Telmisartan 40 is efficacious 5 mg mg safe in Indian subjects with regard to the routine clinical setting.

This will be a multicentre, randomized, double-blind, parallel-Group, comparative active-controlled phase III clinical trial to evaluate the efficacy and safety of fixed-Dose Combination of Bisoprolol 5 m g and Telmisartan 40 mg tablet versus a fixed-Dose combination of Metoprolol Succinate ER 50 mg and Telmisartan 40 mg tablets in subjects with mild to moderate hypertension. Initially, subjects will screened predefined be as per eligibility criteria for the study. The ITT population will include approximately a total number of 264 e ligible female male and of any ethnicity diagnosed with mild to moderate hypertension. Eligible 264 subjects will be either enrolled to receive Fixed-Dose Combination (FDC) of Bisoprolol 5 mg and Telmisartan 40 mg tablet or Fixed-Dose Combination of Metoprolol Succinate ER 50 mg and Telmisartan 40 mg tablets in 1:1 ratio.

#### Test

**Arm: Treatment Arm 1:** Fixed-Dose Combination (FDC) of Bisoprolol 5 mg and Telmisartan 40 mg tablet (n=132)

**Reference Arm: Treatment Arm 2:** Fixed-Dose Combination of Metoprolol Succinate ER 50 mg and Telmisartan 40 mg (n=132)

#### Efficacy:

#### **Primary endpoint**

Percentage of the subjects achieved the target levels of clinical BP among mild to moderate hypertensive subjects (target level: SBP < 140 mm Hg and DBP < 90 mm Hg);

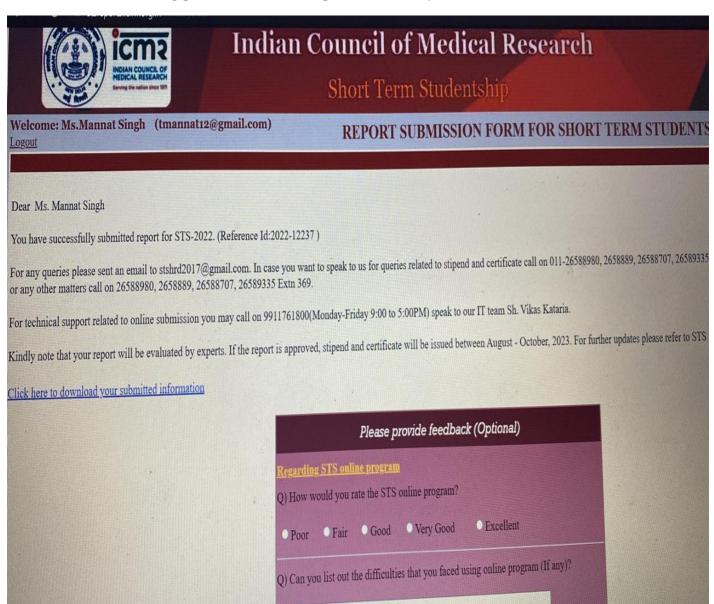
#### Secondary end point

- Mean reduction in systolic and diastolic blood pressure measured in sitting position compared to baseline (After 4, 8 and 12 weeks)
- Proportion of responders after 12 weeks of dosing (Responder rate defined as the proportion of subjects with a decrease in diastolic BP by at least 10 mmHg).
- Reduction in mean heart rate compared to baseline (After 4, 8 and 12 weeks)

#### Safety (Screening visit to end of study visit)

- Adverse Events (AE) assessment
- Physical & systemic examination
- Vital signs
- . Lab abnormalities

#### Oral Hygiene Status among Orthodontic patients - ICMR - 2021-22



Principal Investigator/Co Investigator

Dr. Rajiv Ahluwalia

**Orthodontic** 

## Comparative analysis of nutritional deficiency and stression incidence of recurrent aphthous ulcer in younger age group post pandemic

No. 21/1/2022-HRD-STS Date: 13.03.2023

# ICMR-Short-Term Studentship (STS) 2022 Report Review Result Notification

The ICMR-STS-2022 reports were examined by a panel of Experts. In addition, the administrative review of the Report Attestation Form (RAF) and Institutional Ethics Committee (IEC) approval letters submitted by the students was also done.

The result as given in the list below has been declared as "Approved/Not approved/Withheld" as per the grades assigned by the scientific reviewers and the according to the existing ICMR-STS rules and guidelines:

- Approved: Reports have been accepted. A stipend of Rs. 50,000/- will be issued to the selected students within three months from the date of result declaration, along with an ecertificate in about next six months. Updates will be notified accordingly on the ICMR-STS website and information will also be communicated through emails to the selected students only. The stipend will be released online to the respective bank account of the students with results as "Approved". E-Certificates download link will be available on the ICMR-STS website as per the given timeline mentioned (please do not send emails asking for the same).
- Not Approved: Report has been not approved by Experts upon review, no stipend or certificate will be issued to the students in such a case.
- Withheld: The students did not submit the RAF/IEC as per the valid format required and guidelines and the final approval of their respective result is subject to the submission of the revised RAF/IEC, details of which will be communicated shortly through email only to the withheld students as given in the list below (kindly do not send any emails asking for the reason until and unless communicated by ICMR). If the revised documents as applicable are not submitted by 15th April, 2023 to email address: stshrd2017@gmail.com, then the withheld reports will be declared as "Not approved" without any further correspondences. The final result will be updated accordingly for these withheld students by 20th April, 2023 based on the document re-submission and justification received, which will be reviewed by the ICMR.

S. No.	STS Reference ID	Grades	Result
1	2022-00023	В	Approved
2	2022-00027	С	Approved
3	2022-00033	В	Approved
4	2022-00038	С	Approved
5	2022-00042	С	Approved
6	2022-00048	С	Approved
7	2022-00049	D	Approved
8	2022-00056	D	Approved
9	2022-00059	С	Approved
10	2022-00063	С	Approved
11	2022-00072	D	Approved

Principal Investigator/Co Investigator

Nidhi Gupta

**Pedodontics** 

1327	2022-12137	В	Approved
1326	2022-12137	D	Approved
1325	2022-12101	C	Approved
1324	2022-12033	C	Withheld
1323	2022-12087	E	Not Approved
1322	2022-12083	C	Approved Approved
1321	2022-12070	В	Not Approved Approved
1320	2022-12060	E	Approved
1318	2022-12039	D	Withheld
1318	2022-11966	D	Approved
1316 1317	2022-11952 2022-11966	D C	Approved
1315		2000	Withheld
1314	2022-11934 2022-11939	D	Not Approved
1313	5.	E	Approved
AND STREET	2022-11917 2022-11918	D	Withheld
1311	2022-11913	C	Approved
1310	2022-11904	C	Approved
1310	2022-11883	В	Approved
1308	2022-11883	D	Withheld
1307 1308	2022-11868 2022-11869	C	Approved
1306	2022-11796	С	Approved
1305	2022-11787	С	Approved
1304	2022-11784	С	Approved
1303	2022-11777	С	Approved
1302	2022-11773	D	Approved
1301	2022-11770	D	Approved
1300	2022-11768	В	Approved
1299	2022-11732	С	Approved
1298	2022-11725	С	Approved
1297	2022-11719	D	Approved
1296	2022-11707	D	Approved
1295	2022-11672	С	Approved
1294	2022-11661	E	Not Approved
1293	2022-11609	С	Approved
1292	2022-11599	С	Approved
1291	2022-11598	В	Approved
1290	2022-11594	E	Not Approved
1289	2022-11576	51	Approved
1288	2022-11572	C	Approved
1287	2022-11556	В	Approved
1286	2022-11555	С	Approved
1285	2022-11541	С	Withheld
1284	2022-11540	D	Approved
1283	2022-11526	С	Approved
1282	2022-11525	С	Approved
1281	2022-11510	В	Approved
1001	0000 11510		

