KLE ACADEMY OF HIGHER EDUCATION AND RESEARCH
(Formerly known as KLE University)
(Deemed-to-be-University established u/s 3 of the UGC Act, 1956)
Accredited 'A' Grade by NAAC (2nd Cycle) Placed in Category 'A' by MHRD (GoI)
JNMC Campus, Nehru Nagar, Belagavi-590 010, Karnataka State, India
☎: 0831-2444444 FAX: 0831-2493777 Web: http://www.kledeemeduniversity.edu.in E-mail: info@kledeemeduniversity.edu.in

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

3.2.3.1. Number of research projects/clinical trials funded by government/industries and non-government agencies year-wise during the last five years

HEI Input:

2019-20	2018-19	2017-18	2016-17	2015-16
119	311	159	162	137

Provide the -copies of grant letters with highlighted amount with highlighted amount funded by government/industries and non-government agencies

Answer:
E-copies of the letters of award for the year with highlighted amount with highlighted amount funded by government/industries and non-government agencies.

- Women First: Preconception Maternal Nutrition: A randomized trial
- Aspirin Supplementation for Pregnancy Indicated risk reduction in nulliparous (Aspirin) Trial
- Bioavailability of Arsenic Trioxide when administered orally in Cancer Patients
- Cervical and Breast cancer Screening Camps in North Karnataka.

Dr V. A. Kothiwale
Registrar
REGISTRAR
KLE Academy of Higher Education
and Research, BELAGAVI

SUBCONTRACT
AMENDMENT NUMBER FOUR (4)

Prime Recipient	Subcontractor	
Institution/Organization ("Prime Recipient") Name: Regents of the University of Colorado, a body corporate, for and on behalf of the **University of Colorado Denver** Address: University of Colorado Denver, Office of Grants and Contracts, Anschutz Medical Campus Bldg. 500, W1126, 13001 E 17th Place, Mail Stop F428, Aurora, Colorado 80045	Institution/Organization ("Subcontractor") Name: **Jawaharlal Nehru Medical College** Address: Nehru Nagar, Belgaum Karnataka, India, PIN 590010	
Prime Award No. OPP1055867_YR4	Subcontract No. FY13.040.002	Amount Funded This Action: US$442,578
Prime Recipient's Principal Investigator Nancy Krebs, MD (PI Change)	Amendment No. FY16.115.004 AMD4	Project No. 2-5-81932

This Amendment modifies the following to the Original Terms and Conditions

1. PERIOD

The Current Period of Performance applicable to the Subcontract is extended to cover the Budget Period November 1, 2014 to October 31, 2016.

2. COMPENSATION

The budget available for the Budget Period is revised as follows:

Personnel	US$249,394
Consultant Costs	US$28.560
Supplies	US$62.200
Travel	US$44.696
Total Direct Costs	**US$384,850**
F&A Costs @ 15%	US$57.728
Total Costs	**US$442,578**
Cumulative Costs (Amount Funded to Subcontractor through the end of the Budget Period)	**US$1,462,955**

ATTESTED

Dr. V.A.Kothiwale
Registrar
KLE Academy of Higher Education and Research,
(Deemed-to-be-University u/s 3 of the UGC Act,1956)
Belagavi-590 010,Karnataka

2. PAYMENT

Subcontractor may submit invoices to Prime Recipient, for costs incurred. Said invoices should include:

(a) Subcontract Amendment number: FY16.115.004 AMD4 (JNMC)
(b) Prime Award number: OPP1055867_YR4 (PI CHANGE)
(c) Project number: 2-5-81932
(d) The period for which reimbursement is being requested.
(e) An itemization of current and cumulative costs in accordance with the categories in the budget.
(f) Telephone number for Subcontractor's certifying officer.
(g) All invoices should be signed by Subcontractor's authorized official and include the following statement: *"I certify that all expenditures reported (or payments requested) are for appropriate purposes and in accordance with the provisions of the application and award document."* Promptly after approval of each invoice, Prime Recipient shall make payment thereof.

A final invoice for the Budget Period must be submitted within sixty (60) calendar days after termination or expiration of this Subcontract or the Budget Period, whichever is first, and must be marked "Final Invoice".

Invoices should be mailed to the attention of: Jamie Westcott; University of Colorado Denver; 12700 E, 19th Ave., Campus Box C225; Aurora, Colorado 80045. Jamie Westcott may be reached by telephone at (303) 724-3265.

All other terms and conditions of the Subcontract remain in full force and effect.

By an Authorized Official (UCD OGC) of Prime Recipient:	By an Authorized Official of Subcontractor: (JNMC)
Thomas Keith — 2/17/16	MH — 08/01/2016
Name — Date	Name Dr. N.S. Mahantshetti — Date
Title	Title PRINCIPAL, JNMC
Acknowledged by Principal Investigator (UCD PI) of Prime Recipient	
[signature] — 1-11-16	
Name — Date	
Title Professor	

ATTESTED

Dr. V.A.Kothiwale
Registrar
KLE Academy of Higher Education and Research,
(Deemed-to-be-University u/s 3 of the UGC Act,1956)
Belagavi-590 010,Karnataka

SUBCONTRACT
AMENDMENT NUMBER FIVE (5)

Prime Recipient	Subcontractor	
Institution/Organization ("Prime Recipient") Name: Regents of the University of Colorado, a body corporate, for and on behalf of the **University of Colorado Denver** Address: University of Colorado Denver, Office of Grants and Contracts, Anschutz Medical Campus Bldg. 500, W1126, 13001 E 17th Place, Mail Stop F428, Aurora, Colorado 80045	Institution/Organization ("Subcontractor or Subrecipient") Name: Jawaharlal Nehru Medical College Address: Nehru Nagar, Belgaum Karnataka, India, PIN 590010 DUNS: 650251213	
Prime Award No.: OPP1055867_AMD03	Subcontract No.: FY13.040.002	Amount Funded This Action: USD$160,736
Prime Recipient's Principal Investigator: Nancy Krebs, MD	Amendment No.: FY17.115.007_AMD5	Project No.: 2-5-81932
Project Title: Implementing Integrated Maternal Nutrition Interventions		

1. **PERIOD**

The Current Period of Performance applicable to the Subcontract is extended to cover the Budget Period November 1, 2014 to October 31, 2017.

2. **COMPENSATION**

The budget available for the Budget Period is revised as follows:

Personnel	USD$15,050.93
Consultation Costs	USD$38,102
Supplies	USD$79,169.91
Travel	USD$7447.07
Total Direct Costs	**USD$139,770**
F&A Costs @ 15%	USD$20,966
Total Costs	**USD$160,736**
Total Cumulative Costs (Total amount funded through the budget period)	**USD$1,623,691**

3. **PAYMENT**

Subcontractor may submit invoices to Prime Recipient, for costs incurred. Said invoices should include:

(a) Subcontract Amendment number: FY17.115.007_AMD5 JNMC
(b) Prime Award number: OPP1055867_AMD03
(c) Project number: 2-5-81932
(d) The period for which reimbursement is being requested.
(e) An itemization of current and cumulative costs in accordance with the categories in the budget.
(f) Telephone number for Subcontractor's certifying officer.
(g) All invoices should be signed by Subcontractor's authorized official and include the following statement: *"I certify that all expenditures reported (or payments requested) are for appropriate purposes and in accordance with the provisions of the application and award document."* Promptly after approval of each invoice, Prime Recipient shall make payment thereof.

ATTESTED

Dr. V.A.Kothiwale
Registrar
KLE Academy of Higher Education and Research,
(Deemed-to-be-University u/s 3 of the UGC Act,1956)
Belagavi-590 010,Karnataka

A final invoice for the Budget Period must be submitted within sixty (60) calendar days after termination or expiration of this Subcontract or the Budget Period, whichever is first, and must be marked "Final Invoice".

Invoices should be mailed to the attention of: Jamie Westcott; University of Colorado Denver; 12700 E. 19th Ave., Campus Box C225; Aurora, Colorado 80045. Jamie Westcott may be reached by telephone at (303) 724-3265.

4. REVISED TERM

Paragraph 3 of the Subcontract terms and conditions is deleted in its entirety and is replaced with the following:

A final statement of cumulative costs incurred, including cost sharing, marked "FINAL" must be submitted to UCD's Financial Contact, as shown in Attachments 3A, before the earlier of sixty (60) days after Subaward end date or fifteen (15) days prior to the date UCD's final invoice is required by the Sponsor in the Prime Award. The final statement of costs shall constitute Subcontractor's final financial report.

UNIFORM GUIDANCE/FULL FORCE AND EFFECT

The Subcontract is hereby revised to include any and all applicable changes required by the implementation of 2 C.F.R § 200 UNIFORM ADMINISTRATIVE REQUIREMENTS, COST PRINCIPLES, AND AUDIT REQUIREMENTS FOR FEDERAL AWARDS.

All other terms and conditions of the Subcontract remain in full force and effect.

By an **Authorized Official** of Prime Recipient: **(UCD OGC)** Thomas Keith 1/31/17 Name Date	By an Authorized Official of **Subcontractor:** **(JNMC)** 21/01/17 Name Dr. N.S. Mahantshetti Date
Acknowledged by **Principal Investigator** of Prime Recipient **(UCD PI):** 1/23/17 Name Date	

ATTESTED

Dr. V.A.Kothiwale
Registrar
KLE Academy of Higher Education and Research,
(Deemed-to-be-University u/s 3 of the UGC Act,1956)
Belagavi-590 010,Karnataka

Non-Federal Research Subcontract Amendment

Contractor	Subcontractor
Institution/Organization ("Contractor") **Name:** Regents of the University of Colorado, a body corporate, for and on behalf of the **University of Colorado Denver** **Address:** University of Colorado Denver, Office of Grants and Contracts, Anschutz Medical Campus Bldg. 500, W1126, 13001 E 17th Place, Mail Stop F428, Aurora, Colorado 80045-2571	**Institution/Organization** ("Subcontractor") **Name:** Jawaharlal Nehru Medical College **Address:** Nehru Nagar, Belgaum Karnataka, India, PIN 590010 Award: OPP1055867
Contractor Principal Investigator: Nancy Krebs, MD	**Subcontractor Principal Investigator:** Dr. Shivaprasad S. Goudar
Amendment No.: FY18.115.011_AMD6	**Subcontract No.:** FY13.040.002 **Contractor Project No.:** 2-5-81932
Project Title: Implementing Integrated Maternal Nutrition Interventions	
Subcontract Period of Performance: **Budget Period:** Start: 11/1/2017 End: 10/31/2018 **Total Anticipated Project Period:** Start: 12/1/2012 End: 10/31/2018	**Contract Value:** Funding This Action: $ 144,176 (USD) Total Funding to Date: $ 1,767,867 (USD)

Amendment(s) to Original Terms and Conditions

1. PERIOD
The Subcontract Period of Performance is revised to cover November 1, 2017 to October 31, 2018.
2. BUDGET
The cumulative budget available for the Subcontract Period of Performance is attached.
3. INVOICING
Subcontractor's invoicing requirements are revised to include the following information as it appears in this Amendment: Subcontract Amendment Number; Contractor Project Number; Subcontract Period of Performance; and Contractor Purchase Order Number (if provided by Contractor).

All other terms and conditions of the Subcontract remain in full force and effect.

By an **Authorized Official** of Contractor: Ryan Holland Digitally signed by Ryan Holland DN: cn=Ryan Holland, o=University of Colorado Denver, ou=Office of Grants and Contracts, emailaryan.holland@ucdenver.edu, c=US Date: 2018.01.04 12:14:03 -07'00' 01/04/18 Date	By an Authorized Official of **Subcontractor:** (Dr. N.S Mahantshetti) 4/12/17 Date
Acknowledged by Contractor **Principal Investigator:** 12/14/17 Date	

ATTESTED

Dr. V.A.Kothiwale
Registrar
KLE Academy of Higher Education and Research,
(Deemed-to-be-University u/s 3 of the UGC Act,1956)
Belagavi-590 010,Karnataka

Budget Period:	11/1/2017 to 10/31/2018
Personnel	$53,704.00
Salary	$53,704.00
Benefits	$0.00
Equipment	
Supplies	$70,412.00
Travel	-$420.00
Other Expenses	$1,675.00
Consulting	
Total Direct Costs	**$125,371.00**
Total BASE for F&A	**$125,371.00**
F&A Costs	$18,805.00
15.00%	
*Exclusions	
TOTAL COSTS	**$144,176.00**
TOTAL CUMULATIVE	**$1,767,867.00**

ATTESTED

Dr. V.A.Kothiwale
Registrar
KLE Academy of Higher Education and Research,
(Deemed-to-be-University u/s 3 of the UGC Act,1956)
Belagavi-590 010,Karnataka

Non-Federal Research Subcontract Amendment

Contractor	Subcontractor
Institution/Organization ("Contractor") **Name:** Regents of the University of Colorado, a body corporate, for and on behalf of the **University of Colorado Denver** **Address:** University of Colorado Denver, Office of Grants and Contracts, Anschutz Medical Campus Bldg. 500, W1126, 13001 E 17th Place, Mail Stop F428, Aurora, Colorado 80045-2571	**Institution/Organization** ("Subcontractor") **Name:** Jawaharlal Nehru Medical College **Address:** Nehru Nagar, Belgaum Karnataka, India, PIN 590010 Award: OPP1055867
Contractor Principal Investigator: Nancy Krebs, MD	**Subcontractor Principal Investigator:** Dr. Shivaprasad S. Goudar
Amendment No.: FY19.115.007_AMD7	**Subcontract No.:** FY13.040.002 / **Contractor Project No.:** 2-5-81932
Project Title: Implementing Integrated Maternal Nutrition Interventions	
Subcontract Period of Performance: **Budget Period:** Start: 11/1/2018 End: 1/31/2019 **Total Anticipated Project Period:** Start: 12/1/2012 End: 1/31/2019	**Contract Value:** Funding This Action: $ 29,302 (USD) Total Funding to Date: $ 1,797,169 (USD)

Amendment(s) to Original Terms and Conditions

1. PERIOD
The Subcontract Period of Performance is revised to cover November 1, 2018 to January 31, 2019.
2. BUDGET
The cumulative budget available for the Subcontract Period of Performance is attached.
3. INVOICING
Subcontractor's invoicing requirements are revised to include the following information as it appears in this Amendment: Subcontract Amendment Number; Contractor Project Number; Subcontract Period of Performance; and Contractor Purchase Order Number (if provided by Contractor).

All other terms and conditions of the Subcontract remain in full force and effect.

By an **Authorized Official** of Contractor: Ryan Holland Digitally signed by Ryan Holland DN: cn=Ryan Holland, o=University of Colorado Denver, ou=Office of Grants and Contracts, email=ryan.holland@ucdenver.edu, c=US Date: 2018.10.26 15:58:45 -06'00' 10/26/18 Date	By an Authorized Official of **Subcontractor:** (Dr. N.S Mahantshetti) Date 5/10/18
Acknowledged by Contractor **Principal Investigator:** 10-22-18 Date	

ATTESTED
Dr. V.A.Kothiwale
Registrar
KLE Academy of Higher Education and Research,
(Deemed-to-be-University u/s 3 of the UGC Act,1956)
Belagavi-590 010,Karnataka

Budget Period:	11/1/2018 to 1/31/2019
Personnel	$7,520.00
Salary	$7,520.00
Supplies	$13,520.00
Travel	$4,440.00
Total Direct Costs	**$25,480.00**
Total BASE for F&A	**$25,480.00**
F&A Costs	$3,822.00
15.00%	
*Exclusions	
TOTAL COSTS	**$29,302.00**
TOTAL CUMULATIVE	**$1,797,169.00**

ATTESTED

Dr. V.A.Kothiwale
Registrar
KLE Academy of Higher Education and Research,
(Deemed-to-be-University u/s 3 of the UGC Act,1956)
Belagavi-590 010,Karnataka

Non-Federal Research Subcontract Amendment

Contractor	Subcontractor
Institution/Organization ("Contractor") **Name:** Regents of the University of Colorado, a body corporate, for and on behalf of the **University of Colorado Denver** **Address:** University of Colorado Denver, Office of Grants and Contracts, Anschutz Medical Campus Bldg. 500, W1126, 13001 E 17th Place, Mail Stop F428, Aurora, Colorado 80045-2571	**Institution/Organization** ("Subcontractor") **Name:** Jawaharlal Nehru Medical College **Address:** Nehru Nagar, Belgaum Karnataka, India, PIN 590010 Award: OPP1055867
Contractor Principal Investigator: Nancy Krebs, MD	**Subcontractor Principal Investigator:** Dr. Shivaprasad S. Goudar
Amendment No.: FY19.115.007_AMD7	**Subcontract No.:** FY13.040.002 / **Contractor Project No.:** 2-5-81932
Project Title: Implementing Integrated Maternal Nutrition Interventions	
Subcontract Period of Performance: **Budget Period:** Start: 11/1/2018 End: 1/31/2019 **Total Anticipated Project Period:** Start: 12/1/2012 End: 1/31/2019	**Contract Value:** Funding This Action: $ 29,302 (USD) Total Funding to Date: $ 1,797,169 (USD)

Amendment(s) to Original Terms and Conditions

1. PERIOD
The Subcontract Period of Performance is revised to cover November 1, 2018 to January 31, 2019.
2. BUDGET
The cumulative budget available for the Subcontract Period of Performance is attached.
3. INVOICING
Subcontractor's invoicing requirements are revised to include the following information as it appears in this Amendment: Subcontract Amendment Number; Contractor Project Number; Subcontract Period of Performance; and Contractor Purchase Order Number (if provided by Contractor).

All other terms and conditions of the Subcontract remain in full force and effect.

By an **Authorized Official** of Contractor: Ryan Holland Digitally signed by Ryan Holland DN: cn=Ryan Holland, o=University of Colorado Denver, ou=Office of Grants and Contracts, email=ryan.holland@ucdenver.edu, c=US Date: 2018.10.26 15:58:45 -06'00' 10/26/18 Date	By an Authorized Official of **Subcontractor:** (Dr. N.S. Mahantshetti) Date 5/10/18
Acknowledged by Contractor **Principal Investigator:** 10-22-18 Date	

ATTESTED

Dr. V.A.Kothiwale
Registrar
KLE Academy of Higher Education and Research,
(Deemed-to-be-University u/s 3 of the UGC Act,1956)
Belagavi-590 010,Karnataka

Budget Period:	11/1/2018 to 1/31/2019
Personnel	$7,520.00
Salary	$7,520.00
Supplies	$13,520.00
Travel	$4,440.00
Total Direct Costs	**$25,480.00**
Total BASE for F&A	**$25,480.00**
F&A Costs	$3,822.00
15.00%	
*Exclusions	
TOTAL COSTS	**$29,302.00**
TOTAL CUMULATIVE	**$1,797,169.00**

ATTESTED

Dr. V.A.Kothiwale
Registrar
KLE Academy of Higher Education and Research,
(Deemed-to-be-University u/s 3 of the UGC Act,1956)
Belagavi-590 010,Karnataka

Non-Federal Research Subcontract Amendment

Contractor	Subcontractor
Institution/Organization ("Contractor") **Name:** Regents of the University of Colorado, a body corporate, for and on behalf of the **University of Colorado Denver** **Address:** University of Colorado Denver, Office of Grants and Contracts, Anschutz Medical Campus Bldg. 500, W1126, 13001 E 17th Place, Mail Stop F428, Aurora, Colorado 80045-2571	**Institution/Organization** ("Subcontractor") **Name:** Jawaharlal Nehru Medical College **Address:** Nehru Nagar, Belgaum Karnataka, India, PIN 590010 Award: OPP1055867
Contractor Principal Investigator: Nancy Krebs, MD	**Subcontractor Principal Investigator:** Dr. Shivaprasad S. Goudar
Amendment No.: FY19.115.011 AMD8	**Subcontract No.:** FY13.040.002 / **Contractor Project No.:** 2-5-81932
Project Title: Implementing Integrated Maternal Nutrition Interventions	
Subcontract Period of Performance: **Budget Period:** Start: 11/1/2018 End: 10/31/2019 **Total Anticipated Project Period:** Start: 12/1/2012 End: 10/31/2019	**Contract Value:** Funding This Action: $ 16,100 (USD) Total Funding to Date: $ 1,813,269 (USD)

Amendment(s) to Original Terms and Conditions

1. PERIOD
The Subcontract Period of Performance is revised to cover November 1, 2018 to October 31, 2019.
2. BUDGET
The cumulative budget available for the Subcontract Period of Performance is attached.
3. INVOICING
Subcontractor's invoicing requirements are revised to include the following information as it appears in this Amendment: Subcontract Amendment Number; Contractor Project Number: Subcontract Period of Performance: and Contractor Purchase Order Number (if provided by Contractor).

All other terms and conditions of the Subcontract remain in full force and effect.

By an **Authorized Official** of Contractor: Eric Maize 4/3/2019 Date	By an Authorized Official of **Subcontractor**: (DR NS. MAHANTSHETTI) 28/03/2019 Date
Acknowledged by Contractor **Principal Investigator:** 3/29/19 Date	

ATTESTED
Dr. V.A.Kothiwale
Registrar
KLE Academy of Higher Education and Research,
(Deemed-to-be-University u/s 3 of the UGC Act,1956)
Belagavi-590 010,Karnataka

Budget Period:	11/1/2018 to 10/31/2019
Travel	$4,000.00
Other Expenses (List below)	$10,000.00
Consulting	
Total Direct Costs	**$14,000.00**
Total BASE for F&A	**$14,000.00**
F&A Costs	$2,100.00
15.00%	
*Exclusions	
TOTAL COSTS	**$16,100.00**
TOTAL CUMULATIVE	**$1,813,269.00**

ATTESTED

Dr. V.A.Kothiwale
Registrar
KLE Academy of Higher Education and Research,
(Deemed-to-be-University u/s 3 of the UGC Act,1956)
Belagavi-590 010,Karnataka

Non-Federal Research Subcontract Amendment

Contractor	Subcontractor
Institution/Organization ("Contractor") **Name:** Regents of the University of Colorado, a body corporate, for and on behalf of the **University of Colorado Denver** **Address:** University of Colorado Denver, Office of Grants and Contracts, Anschutz Medical Campus Bldg. 500, W1126, 13001 E 17th Place, Mail Stop F428, Aurora, Colorado 80045-2571.	**Institution/Organization** ("Subcontractor") **Name:** Jawaharlal Nehru Medical College **Address:** Nehru Nagar, Belgaum Karnataka, India, PIN 590010 Award: OPP1055867
Contractor Principal Investigator: Nancy Krebs, MD	**Subcontractor Principal Investigator:** Dr. Shivaprasad S. Goudar
Amendment No.: FY20.115.006_AMD9	**Subcontract No.:** FY13.040.002 / **Contractor Project No.:** 2-5-81932
Project Title: Implementing Integrated Maternal Nutrition Interventions	
Subcontract Period of Performance: **Budget Period:** Start: 11/01/2019 End: 10/31/2020 **Total Anticipated Project Period:** Start: 12/1/2012 End: 10/31/2020	**Contract Value:** Funding This Action: $ 0 (NCE) Total Funding to Date: $ $1,813,269

Amendment(s) to Original Terms and Conditions

1. PERIOD
The Subcontract Period of Performance is extended to cover November 1st, 2019 to October 31st, 2020.
2. BUDGET
This is a no cost extension. No additional monies will be provided. For the services provided hereunder during the Budget Period, Contractor will reimburse Subcontractor for all reasonable, allocable, and allowable costs incurred up to, but not to exceed One Million, Eight Hundred and Thirteen Thousand, Two Hundred and Sixty-Nine ($1,813,269.00). Under no circumstances shall Contractor be responsible for paying Subcontractor in excess of $1,813,269.00 for the Budget Period, November 1st, 2019 to October 31st, 2020.
3. INVOICING
Subcontractor's invoicing requirements are revised to include the following information as it appears in this Amendment: Subcontract Amendment Number; Contractor Project Number; Subcontract Period of Performance; and Contractor Purchase Order Number (if provided by Contractor).

All other terms and conditions of the Subcontract remain in full force and effect.

By an **Authorized Official** of Contractor: Ryan Holland Digitally signed by Ryan Holland DN: cn=Ryan Holland, o=University of Colorado Denver, ou=Office of Grants and Contracts, email=ryan.holland@ucdenver.edu, c=US Date: 2019.11.12 08:27:23 -07'00' Date	By an Authorized Official of **Subcontractor**: 21/10/2019 Date
Acknowledged by Contractor **Principal Investigator:** 10/23/19 Date	ATTESTED Dr. V.A.Kothiwale Registrar KLE Academy of Higher Education and Research, (Deemed-to-be-University u/s 3 of the UGC Act,1956) Belagavi-590 010,Karnataka

Research Agreement
Amendment

Prime Recipient	Subrecipient
Institution/Organization ("Prime Recipient") Name: Christiana Care Health Services, Inc Address: Office of Sponsored Programs Suite 2400 200 Hygeia Drive Newark, DE 19713	*Institution/Organization ("Subrecipient")* Name: Jawaharlal Nehru Medical College (JNMC) KLE Organization Address: Nehru Nagar, Belgaum 5900-10 Karnataka, India
Principal Investigator (PI): Richard Derman, MD	Principal Investigator : Dr. Bhalachandra Kodkany

Prime Award No.	FAIN	Federal Awarding Agency:
5U10HD076457-03	U10HD076457	Eunice Kennedy Shriver National Institute of Child Health & Human Development of the National Institutes of Health

Project Title: CCHS-JNMC Global Network for Women's & Children's Health Research Unit

Subaward Period of Performance:	Amount Funded	Amendment No.	Subaward No.
Start Date: 05/01/2015 End Date: 04/30/2016	This Action: $455,150.00	5	601937

Effective Date of Amendment	Total Amount of Federal Funds Obligated to date:	Subject to FFATA
May 1, 2015	$1,820,261.00	Yes ☒ or No ☐

Amendment(s) to Original Terms and Conditions
This Amendment revises the above-referenced Research Subaward Agreement as follows:

Check mark(s) for items 1-7 indicate the changes affected by this amendment.

1. ☒ The period of performance is changed to read as follows:
   From Start Date: 05/01/2015
   Through End Date: 04/30/2016
2. ☐ No extension of time
3. ☐ Please send invoices to:
4. ☐ No increase in the total amount funded to date.
5. ☒ The funding for this Subaward is changed to read as follows:
   Amount funded this action: .....$ 455,150
   Amount of prior funding: .....$ 1,365,111
   Total amount funded to date: .....$ 1,820,261
6. ☐ The cost sharing commitment under this Subaward is changed to read as follows:
   Cost share commitment this action: .....$
   Total Cost share committed: .....$
7. ☐ A "Key Person" identified in the Subaward is changed as follows:
8. ☒ Other: This Amendment #5 incorporates the Notice of Award 5U10HD076457-03. Also, Attachment 1 to this Amendment #5 presents the JNMC budget for the period May 1, 2015-April 30, 2016.
9. ☒ Except as modified herein, all other terms and conditions of this Subaward Agreement remain in full force and effect.

By an Authorized Official of Prime Recipient:	By an Authorized Official of Subrecipient:
Name: Thomas L. Corrigan	Name: Dr. N.S. Mahantashetti
Title: Chief Financial Officer	Title: Principal
Date: 6-4-15	Date: 10/06/15

April 2011 DP

APPROVED BY LEGAL

ATTESTED

Dr. V.A. Kothiwale
Registrar
KLE Academy of Higher Education and Research,
(Deemed-to-be-University u/s 3 of the UGC Act,1956)
Belagavi-590 010,Karnataka

Attachment 1
Subaward Agreement Amendment 5

1. The following will be added to Attachment 5 of the Subaward Agreement:

The JNMC budget for the period May 1, 2015-April 30, 2016 is:

JNMC Component	*Direct Costs*	*Indirect Costs (8%)*	*Total Costs*
Base Operations (a)	73,166	5,853	79,019
Protocol Funds (b)	348,269	27,862	376,131
TOTAL, Both Components	$ 421,435	$ 33,715	$ 455,150

NOTES AND CONDITIONS

(a) The direct cost amount of $73,166 is the maximum amount that can be awarded to JNMC for base operations due to the $155,000 cap applicable to the combined direct cost total for CCHS and JNMC base operations.

(b) Protocol funds may be spent for (a) the Maternal Newborn Health Registry, (b) the new study referred to as ASPIRIN, and (c) for miscellaneous protocol expenses (e.g., travel required for Steering Committee meetings or mandatory training of a data manage or a country coordinator for a protocol when the expenses are protocol-related but not related to MNHR or ASPIRIN). Invoicing must be done separately for each of these 3 components utilizing a PI-approved template and sub-component budget. The sub-component budgets may be revised upon PI approval to re-allocate funds to protocol sub-components as may be needed to accomplish Global Network objectives.

ATTESTED

Dr. V.A.Kothiwale
Registrar
KLE Academy of Higher Education and Research,
(Deemed-to-be-University u/s 3 of the UGC Act,1956)
Belagavi-590 010,Karnataka

Notice of Award

COOPERATIVE CLINICAL RESEARCH AGREEMENT **Federal Award Date:** 05/04/2015

Department of Health and Human Services
National Institutes of Health
EUNICE KENNEDY SHRIVER NATIONAL INSTITUTE OF CHILD HEALTH & HUMAN DEVELOPMENT

Grant Number: 5U10HD076457-03
FAIN: U10HD076457

Principal Investigator(s):
RICHARD J DERMAN, MD

Project Title: CCHS-JNMC Global Network for Women's & Children's Health Research Unit

INTERIM DIR OFFICE OF SPON PROG
CHRISTIANA CARE HLTH SERV INC
200 HYGEIA DR, STE 2300
NEWARK, DE 19713

Award e-mailed to: RMcMurray@christianacare.org

Period Of Performance:
Budget Period: 05/01/2015 – 04/30/2016
Project Period: 07/01/2013 – 04/30/2018

Dear Business Official:

The National Institutes of Health hereby awards a grant in the amount of $583,138 (see "Award Calculation" in Section I and "Terms and Conditions" in Section III) to CHRISTIANA CARE HEALTH SERVICES, INC. in support of the above referenced project. This award is pursuant to the authority of 42 USC 241 31 USC 6305 42 CFR 52 and is subject to the requirements of this statute and regulation and of other referenced, incorporated or attached terms and conditions.

Acceptance of this award including the "Terms and Conditions" is acknowledged by the grantee when funds are drawn down or otherwise obtained from the grant payment system.

Each publication, press release, or other document about research supported by an NIH award must include an acknowledgment of NIH award support and a disclaimer such as "Research reported in this publication was supported by the Eunice Kennedy Shriver National Institute Of Child Health & Human Development of the National Institutes of Health under Award Number U10HD076457. The content is solely the responsibility of the authors and does not necessarily represent the official views of the National Institutes of Health." Prior to issuing a press release concerning the outcome of this research, please notify the NIH awarding IC in advance to allow for coordination.

Award recipients must promote objectivity in research by establishing standards that provide a reasonable expectation that the design, conduct and reporting of research funded under NIH awards will be free from bias resulting from an Investigator's Financial Conflict of Interest (FCOI), in accordance with the 2011 revised regulation at 42 CFR Part 50 Subpart F. The Institution shall submit all FCOI reports to the NIH through the eRA Commons FCOI Module. The regulation does not apply to Phase I Small Business Innovative Research (SBIR) and Small Business Technology Transfer (STTR) awards. Consult the NIH website http://grants.nih.gov/grants/policy/coi/ for a link to the regulation and additional important information.

If you have any questions about this award, please contact the individual(s) referenced in Section IV.

Sincerely yours,

ATTESTED

Dr. V.A.Kothiwale
Registrar
KLE Academy of Higher Education and Research,
(Deemed-to-be-University u/s 3 of the UGC Act,1956)
Belagavi-590 010,Karnataka

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Mario Martinez
Grants Management Officer
EUNICE KENNEDY SHRIVER NATIONAL INSTITUTE OF CHILD HEALTH & HUMAN DEVELOPMENT

Additional information follows

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SECTION I – AWARD DATA – 5U10HD076457-03

Award Calculation (U.S. Dollars)

Salaries and Wages	$58,040
Fringe Benefits	$13,156
Personnel Costs (Subtotal)	$71,196
Supplies	$250
Travel Costs	$10,000
Other Costs	$388
Consortium/Contractual Cost	$455,150
Federal Direct Costs	$536,984
Federal F&A Costs	$46,154
Approved Budget	$583,138
Total Amount of Federal Funds Obligated (Federal Share)	$583,138
TOTAL FEDERAL AWARD AMOUNT	$583,138
AMOUNT OF THIS ACTION (FEDERAL SHARE)	$583,138

SUMMARY TOTALS FOR ALL YEARS		
YR	THIS AWARD	CUMULATIVE TOTALS
3	$583,138	$583,138
4	$718,138	$718,138
5	$718,138	$718,138

Recommended future year total cost support, subject to the availability of funds and satisfactory progress of the project

Fiscal Information:

CFDA Name:	Child Health and Human Development Extramural Research
CFDA Number:	93.865
EIN:	1510103684A2
Document Number:	UHD076457A
PMS Account Type:	G (Pooled)
Fiscal Year:	2015

IC	CAN	2015	2016	2017
HD	8014707	$583,138	$718,138	$718,138

Recommended future year total cost support, subject to the availability of funds and satisfactory progress of the project

NIH Administrative Data:
PCC: PPB -TR / **OC:** 414P / **Released:** MARTINEZM 04/30/2015
Award Processed: 03/23/2015 01:36:12 PM

SECTION II – PAYMENT/HOTLINE INFORMATION – 5U10HD076457-03

For payment and HHS Office of Inspector General Hotline information, see the NIH Home Page at http://grants.nih.gov/grants/policy/awardconditions.htm

SECTION III – TERMS AND CONDITIONS – 5U10HD076457-03

This award is based on the application submitted to, and as approved by, NIH on the above-titled project and is subject to the terms and conditions incorporated either directly or by reference in the following:

a. The grant program legislation and program regulation cited in this Notice of Award.
b. Conditions on activities and expenditure of funds in other statutory requirements, such as those included in appropriations acts.
c. 45 CFR Part 75.
d. National Policy Requirements and all other requirements described in the NIH Grants

ATTESTED

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Policy Statement, including addenda in effect as of the beginning date of the budget period.

e. Federal Award Performance Goals: As required by the periodic report in the RPPR or in the final progress report when applicable.
f. This award notice, INCLUDING THE TERMS AND CONDITIONS CITED BELOW.

(See NIH Home Page at http://grants.nih.gov/grants/policy/awardconditions.htm for certain references cited above.)

Research and Development (R&D): All awards issued by the National Institutes of Health (NIH) meet the definition of "Research and Development" at 45 CFR Part§ 75.2. As such, auditees should identify NIH awards as part of the R&D cluster on the Schedule of Expenditures of Federal Awards (SEFA). The auditor should test NIH awards for compliance as instructed in Part V, Clusters of Programs. NIH recognizes that some awards may have another classification for purposes of indirect costs. The auditor is not required to report the disconnect (i.e., the award is classified as R&D for Federal Audit Requirement purposes but non-research for indirect cost rate purposes), unless the auditee is charging indirect costs at a rate other than the rate(s) specified in the award document(s).

Carry over of an unobligated balance into the next budget period requires Grants Management Officer prior approval.

This award is subject to the requirements of 2 CFR Part 25 for institutions to receive a Dun & Bradstreet Universal Numbering System (DUNS) number and maintain an active registration in the Central Contractor Registration. Should a consortium/subaward be issued under this award, a DUNS requirement must be included. See http://grants.nih.gov/grants/policy/awardconditions.htm for the full NIH award term implementing this requirement and other additional information.

This award has been assigned the Federal Award Identification Number (FAIN) U10HD076457. Recipients must document the assigned FAIN on each consortium/subaward issued under this award.

Based on the project period start date of this project, this award is likely subject to the Transparency Act subaward and executive compensation reporting requirement of 2 CFR Part 170. There are conditions that may exclude this award; see http://grants.nih.gov/grants/policy/awardconditions.htm for additional award applicability information.

In accordance with P.L. 110-161, compliance with the NIH Public Access Policy is now mandatory. For more information, see NOT-OD-08-033 and the Public Access website: http://publicaccess.nih.gov/.

Treatment of Program Income:
Additional Costs

SECTION IV – HD Special Terms and Conditions – 5U10HD076457-03

NIH staff has determined that the submitted Continuation Progress Report is within the approved scope of work.

****

This award reflect a $135,000 adjustment in the level of support. These funds will be provided to the Research Triange Institute (RTI International) the network's Data Coordinating Center, to cover the Aspirin Drug Cost.

****

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This award is issued as a cooperative agreement, a financial assistance mechanism in which substantial NIH scientific and/or programmatic involvement is anticipated in the performance of the activity. This award is subject to the terms and conditions of award as set forth in the SPECIAL REQUIREMENTS section of RFA-HD- 13-006, "Global Network for Women's and Children's Health Research U10" posted date May 31st, 2012, which are hereby incorporated by reference as special terms and conditions of award.

Copies of this RFA are available at http://www.nih.gov/grants/guide/index.html

****

These special terms and conditions of award are in addition to, and not in lieu of, otherwise applicable OMB administrative guidelines; Federal Regulations, including HHS Grant Administration Regulations at 42 CFR Part 52, 45 CFR Parts 74 and 92; other HHS regulations; and the NIH Grants Policy Statement (rev. 10/13).

****

Project Scientist Contact Information:

Project Scientist: Dr. Marion Koso-Thomas

Email: kosomarl@mail.nih.gov **Phone:** (301) 435-6878

****

This award includes a base budget as described in the RFA HD-13-006 and fixed protocol-specific funding. The average protocol funding rate was calculated based on budgets submitted by the Research Units on the estimated cost per patient for enrollment and conduct of the individual research protocol. Protocol costs include funds for study start up, e.g., training expenses to implement the study, and funds for the conduct of the study (which requires IRB approval).

****

Based on participation, compliance, and performance in protocol activities by the network sites, the protocol funds may be reduced and/or redistributed depending on the needs of the Global Network as a whole.

****

This award includes $455,150 for the following site: Jawaharial Nehru Medical College of KLE University in Belgaum, INDIA.

****

This award includes funds awarded for consortium activity with the Jawaharial Nehru Medical College of KLE University in Belgaum, INDIA in the amount of $455,150.

Consortia are to be established and administered as described in the NIH Grants Policy Statement (rev. 3/15) (http://grants.nih.gov/grants/policy/nihgps/nihgps.pdf).

****

NIH requires the use of the eRA Research Performance Progress Report (RPPR) Module for the submission of all Non-Competing Continuation (Type 5) Progress Reports. See NIH Guide Notice NOT-OD-15-014 (http://grants.nih.gov/grants/guide/notice-files/NOT-OD-15-014.html).

****

ATTESTED

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Belagavi-590 010,Karnataka

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STAFF CONTACTS

The Grants Management Specialist is responsible for the negotiation, award and administration of this project and for interpretation of Grants Administration policies and provisions. The Program Official is responsible for the scientific, programmatic and technical aspects of this project. These individuals work together in overall project administration. Prior approval requests (signed by an Authorized Organizational Representative) should be submitted in writing to the Grants Management Specialist. Requests may be made via e-mail.

Grants Management Specialist: Kimberly Durkin
Email: kimberly.durkin@nih.gov **Phone**: 301-451-0820

Program Official: Tonse N. Raju
Email: rajut@mail.nlh.gov **Phone**: (301) 402-1872 **Fax**: (301) 496-3790

SPREADSHEET SUMMARY
GRANT NUMBER: 5U10HD076457-03

INSTITUTION: CHRISTIANA CARE HEALTH SERVICES, INC.

Budget	Year 3	Year 4	Year 5
Salaries and Wages	$58,040	$58,040	$58,040

Fringe Benefits	$13,156	$13,156	$13,156
Personnel Costs (Subtotal)	$71,196	$71,196	$71,196
Supplies	$250	$250	$250
Travel Costs	$10,000	$10,000	$10,000
Other Costs	$388	$388	$388
Consortium/Contractual Cost	$455,150	$590,150	$590,150
TOTAL FEDERAL DC	$536,984	$671,984	$671,984
TOTAL FEDERAL F&A	$46,154	$46,154	$46,154
TOTAL COST	$583,138	$718,138	$718,138

Facilities and Administrative Costs	Year 3	Year 4	Year 5
F&A Cost Rate 1	56.4%	56.4%	56.4%
F&A Cost Base 1	$81,834	$81,834	$81,834
F&A Costs 1	$46,154	$46,154	$46,154

ATTES...

Dr. V.A.Kothiwale
Registrar
KLE Academy of Higher Education and Research
(Deemed-to-be-University u/s 3 of the UGC Act,195...
Belagavi-590 010,Karnataka

MEMORANDUM OF UNDERSTANDING

BETWEEN

RASAYU CANCER CLINIC, B-1, AMRUT KUMBHA, LAKSHMI PARK SOCIETY, NAVIPETH PUNE

AND

KLE UNIVERSITY'S
SHRI B.M. KANKANAWADI AYURVEDA MAHAVIDYALAYA
SHAHAPUR, BELAGAVI, KARNATAKA.

For

Establishment of Cancer OPD at KLE Ayurveda Hospital
And Research Activities

MEMORANDUM OF UNDERSTANDING

ATTESTED

Dr. V.A.Kothiwale
Registrar
KLE Academy of Higher Education and Research,
(Deemed-to-be-University u/s 3 of the UGC Act,1956)
Belagavi-590 010,Karnataka

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This Memorandum of Understanding ("**MoU**") dated this 11th day of July 2017

by and between:

KLEU's Shri B M Kankanawadi Ayurveda Mahavidyalaya & KLE Ayurveda hospital, Belagavi is a leading institute in offering super speciality quality health care in field of Ayurveda in India., having its office at Nathpai circle, Shahapur, Belagavi (here in after referred to as '**KLE Ayurveda hospital'**) which expression shall unless it be repugnant to the context or meaning there of shall be deemed to mean and include its successors and permitted assigns) of the **One Part**

AND

Rasayu cancer clinic having its place of business at B-1 Amrut kumbha,Lakshmipark society, Navipeth Pune .(here in after referred to as '**RCC**' which expression shall unless it be repugnant to the context or meaning thereof shall be deemed to mean and include its successors and permitted assigns) of the **Other Part**

KLE Ayurveda hospital and RCC shall be individually here in after referred to as '**Party**' and collectively as '**Parties**'.

Where as

A. 'KLE Ayurveda hospital' is a Teaching Ayurveda hospital providing vide range of super-specialty healthcare facilities to Patients.

B. 'RCC' is engaged in specialised Ayurveda based cancer therapies to cancer patients and cancer survivors. These facilities include but are not limited to offering Ayurveda consultation, preparing Ayurveda medicines and dietary supplements for these patients, Panchakarma therapies, offering diet, yoga and psychology consultation.

C. The parties are interested in exploring possible opportunities of establishing a mutually cooperative and beneficial relationship, including the carrying out of Projects relevant to their respective capabilities in India.

D. KLE Ayurveda hospital and RCC, confirm and understand that this MOU is not intended to provide and set out any contractual terms binding or otherwise

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governing the terms and conditions or the manner of conduct of any Projects and that may necessarily require the Parties to:

- share relevant information on a confidential basis with the aim and objective of identifying their requirements, needs and capabilities;
- establish a working relationship between themselves (which is targeted to the parties' specific needs);
- establish Projects which may be of mutual benefits and interest;
- Determine the details of Projects, their scope and purview, Project work plan, funding of the Project, their rights, duties and obligations in relation to the Project and its outcome.

For the purposes of each Project, the Parties shall enter into separate Agreements.

For the purposes of this MOU, "**Project**" shall mean a collaboration relating to Establishing specialty cancer OPD for development of Standard Treatment Protocol's in Cancer Management through specialized Ayurveda consultation and therapies for cancer patient at the premise of KLE Ayurveda hospital, Shahapur, Belagavi.

1. SCOPE OF THE MOU

1.1 The Parties will co-operate to:

(a) Establish facilities for offering specialized Ayurveda consultation to cancer patients which includes offering Ayurveda, yoga, diet and psychological consultation; preparing personalized medicines and dietary supplements for cancer Patients.

(b) Conduct cancer awareness drives, campaigns and lectures for common public and patients.

(c) Conducting various oncology based training programs for Medical students and professionals.

(d) Conduct an annual review of current and future Projects approximately one (1) week prior to the anniversary of the execution of this MOU.

1.2 Subject to the terms and conditions of any Collaboration Agreement agreed to and executed, each Party will have the right, in any field related to the Project or otherwise, to:

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(a) conduct business or research independently, whether or not with third parties;

(b) continue existing commitments, or make new ones;

(c) Exploit or otherwise take advantage of its intellectual property.

2. COLLABORATION AGREEMENT

2.1 The Parties acknowledge and confirm their intention to negotiate and settle the terms and conditions of a Collaboration Agreement in respect of each Project.

2.2 The parties agree that the ownership of the intellectual property rights arising out collaboration will be jointly shared between RCC & KLE. Publications, Authorship rights of involved Doctors/Consultants will be protected. Freedom for conducting individual OPD and Research & Developing new protocols on their own.

2.3 Each Collaboration Agreement will include provisions relating amongst other things to:

(a) A Project plan pursuant to which the Project will be carried out which will include information pertaining to technical objectives, statement of work, deliverables, schedule, decision gates, resource requirements and costs;

(b) Funding arrangements for the Project;

(c) Holding by the Parties of periodic Project review meetings to assess the management and the progress of the Project and the status of any expenditure;

(d) Exploitation of Intellectual property and rights arising from the same including their protection, enforcement and commercialization.

(e) Commercial arrangements between the KLE Ayurveda hospital and RCC.

2.4 The Parties agree, acknowledge and confirm that for any agreement to be binding on them, it must be in writing and shall be executed by a duly authorized representative of each of the KLE Ayurveda hospital and RCC.

ATTESTED

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2.5 KLE Ayurveda hospital will provide basic infrastructure/facilities required for offering patient care which include consultation, treatment procedure, inpatient hospitalisation, investigations, dispensing medicines and dietary supplements and collecting treatment charges. KLE will establish speciality Cancer OPD for Ayurveda management. KLE will provide OPD facility in it to RCC for their expert consultancy as per mutual understanding and permit to prescribe the proprietary/ Research formulations of RCC and protect the confidentiality of RCC.

2.6 KLE Ayurveda hospital will make necessary arrangements for offering medical care and consultation by qualified Ayurveda physician trained in RCC Treatment protocol, to patients approaching for treatment in the collaborative RCC and KLE cancer OPD. Consultant from KLEU in Speciality Cancer OPD will have freedom to plan for different protocols and medications based on the clinical case otherwise RCC standard protocol will be used.

2.7 KLE Ayurveda hospital will make necessary arrangements to avail expert medical opinion or to refer the patient to appropriate medical facilities in case of any emergencies.

2.8 KLE Ayurveda hospital will make arrangements to procure medicines manufactured by Ayurved Rasayani, as required for the collaborative RCC and KLE cancer OPD.

2.9 RCC will offer appropriate training in Ayurveda oncology to doctors deputed by KLE Ayurveda hospital. The number of doctors at a given point of time will not exceed two (2).

2.9 RCC will periodically depute a trained qualified Ayurveda physician so as to provide direct consultation to patients approaching the collaborative RCC and KLE cancer OPD. This doctor will visit KLE Ayurveda hospital at least once in a month. The travel expenses for this visit will be totally beared by RCC.

2.10 KLE Ayurveda hospital will be conducting regular awareness activities about the collaborative RCC and KLE cancer OPD. These activities includes Awareness programs, lectures, pamphlets, banners, newspaper articles and Radio broadcast. KLE Ayurveda hospital will bear all the expenses of such activities.

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2.11 If required for the betterment of patient, RCC will make necessary arrangement to provide online/skype consultation to these patients in Belgaum.

2.12 The responsibility for providing best possible treatment for patient and ensuring his wellbeing lies entirely with the treating physician.

3. REPRESENTATIVE

3.1 For the term and purposes of this MOU, each party shall appoint a designated representative ("the **Representative**").

3.2 The Representative of the appointing Party will be responsible for:

a) managing, overseeing or coordinating that Party's relationship with the other Party;

b) identifying any commercial issues that arise between the Parties and refer them to the **Competent Authority** within the Representative's organization;

c) discussing any issues arising out of this MOU or a Collaboration Agreement with the Representative of the other party; and

d) Co-coordinating the exchange of information between the Parties.

3.3 The Representatives designated at the time of signing this MOU by the parties are:

(a) for KLE Ayurveda hospital:

Name: Dr B S Prasad.

Designation: Medical Director

Email: kleayurvedahospital@gmail.com

Mob. 9448569289.

(b) for RCC

Name: Dr. Avinash Kadam

Designation: Administrator.

Email: avinashk@rbpl.co.in

Mob. 9970259583

4. CONFIDENTIAL INFORMATION

ATTESTED

Dr. V.A.Kothiwale
Registrar
KLE Academy of Higher Education and Research,
(Deemed-to-be-University u/s 3 of the UGC Act,1956)
Belagavi-590 010,Karnataka

4.1 **Definition:** As used herein **Confidential Information**" shall mean and include all information and data which has been provided/disclosed/shared by RCC to KLE Ayurveda hospital prior and post the execution of this MOU and/or the Collaboration Agreement either written or oral or in any other form or manner of communication or which has been acquired or will be acquired by either Party such as designs, drawings, specifications, technical information, documents and know-how, designs, manufacturing processes, ideas, data, financial information and other technologies, whether patentable, copyrightable or susceptible to any other form of protection. The terms and existence of this MOU, the fact that Confidential Information has been shared and/or made available, that discussions or negotiations pertaining to the technology are taking place between the Parties shall also be considered Confidential Information for the purposes of this MOU.

4.2 **Purpose:** The Parties shall use the Confidential Information strictly and solely for the purposes the Confidential Information is provided under this MOU and none other.

4.3 **Ownership:** The Parties hereby understand, acknowledge, andonfirm that the Confidential Information is a valuable trade secret owned by each Party and which retains all right, title, and interest in and unto the same. Neither Party shall have any right, title and interest in the Confidential Information of the other Party. By virtue of either Party disclosing the Confidential Information, no license to such Confidential information or any Intellectual Property rights owned by that Party is or are granted to the other Party. Neither Party shall directly or indirectly, through its directors, employees or agents, at any point of time, do any acts, things or deeds that may prejudicially affect the proprietary right, title and interests of either Party in and unto the Confidential Information.

4.4 **No Warranties:** At no point of time shall either Party be responsible for any loss or damages which may be suffered by the Party receiving the Confidential Information or for that matter by its customers or any third parties on account of or arising from the use of the Confidential Information. Neither Party makes any representations or warranties of any kind, whether expressed or implied as to the accuracy or completeness of the Confidential Information.

ATTESTED

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4.5 **Use of Confidential Information:** Each Party may use the Confidential Information for the purposes stated in Clause 4.2 above only. Each Party recognizes that this MOU imposes an affirmative duty on the other Party to hold such information in confidence and to protect it from dissemination to and use by any and all unauthorized parties. In the absence of any prior written consent neither Party shall copy, reproduce or disclose the Confidential Information to any third party in any manner whatsoever.

4.6 **Further Responsibility**: The Parties agree and undertake to use the same degree of care to protect the confidentiality of the Confidential Information as it would exercise to protect its own trade secrets and information but in no case less than a reasonable degree of care. Each Party may grant access to the Confidential Information to its directors, officers, employees, advisors and consultants ("**related parties**") who have a clear need to know, for purposes of this MOU and shall advise such related parties of the existence and terms of this MOU and of its obligations of confidentiality herein. MoU shall lead to standard clinical protocols in management of cancer which will be asset of both the institutions. Each organisation will have the right to continue or utilize the products, protocols developed during the collaboration even after termination of MoU.

4.7 **Return of Confidential Information**Promptly following the request of either Party the receiving Party will return to the disclosing Party or certify in writing to the disclosing Party as to the destruction of (without retaining any copy in any form or manner) all Confidential Information including copies and extracts thereof as may have been or will be furnished as by the disclosing Party to the receiving Party. But the Hospital records/ data and pharmacy data will be archived to oblige hospital/ pharmacy regulations.

4.8 **Remedies:** The Parties acknowledge, understand and confirm that the disclosing Party is the proprietor of the Confidential Information and that any unauthorized disclosure, misappropriation or unauthorized use of such Confidential Information by the receiving Party in any manner whatsoever will cause serious irreparable loss and harm to disclosing Party. The receiving Party expressly agrees that the disclosing Party shall be entitled to seek injunctive and other

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equitable relief against it to prevent the breach or further breaches of any of its confidentiality obligations under this MOU and which it will not dispute by challenging the jurisdiction of the competent Courts where injunctive or equitable relief is being sought at by the disclosing Party.

5. TERMINATION AND AMENDMENT

The term of this MOU is a period of one (1) year from the date of execution. The MOU will be automatically renewed for a further period of one (1) year unless one Party notifies the other Party in writing 30 days in advance that they do not wish to renew the MOU at the completion of the annual review of current and future projects.

5.1 his MOU may be terminated by mutual consent of the parties. Either party may terminate this MOU upon one (1) month written notice to the other.

5.2 A Collaboration Agreement made pursuant to clause 2 of this MOU shall survive termination or expiration of this MOU.

5.3 This MOU may be amended only by an agreement in writing between the Parties and not otherwise.

6. GENERAL

6.1 KLE Ayurveda hospital and RCC agree that each of them is free to undertake R&D and business projects on their own or in conjunction with third party, and that the Parties will co-operate only in circumstances where each of them agrees if co-operation is for their mutual benefit and each is satisfied that the specific provisions covering their co-operation are appropriate and will not adversely or prejudicially affect their interests.

6.2 With the exception of Clause 4 herein, this MOU is not binding and the Parties do not intend that it or any part of it be binding. It serves only as a record of the understanding between the Parties' intentions pending possible execution of a Collaboration Agreement as contemplated by Clause 2 herein.

6.3 Nothing in this MOU will oblige or cast any obligation upon either Party to enter into a Collaboration Agreement with the other Party or to conduct any Project.

7. This MOU constitutes the entire understanding between the Parties regarding the subject matters contained herein. Any prior agreements,

ATTESTED

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commitments or negotiations concerning the subject matters herein are superseded.

8. The headings contained herein are for the purposes of convenience only and are not intended to define or limit the contents of the provisions contained therein.

9. If one or more provisions of this MOU are held to be illegal or unenforceable,
such provisions will be limited or excluded to the minimum extent required so that this MOU will otherwise remain enforceable in accordance with the remaining terms.

10. The rights of the Parties hereto shall not be prejudiced or restricted by any
indulgence or forbearance extended to the other party and no waiver by the parties hereto of any breach of the other party of any of the terms hereunder shall operate as a waiver in respect of any subsequent breach. No variation of this MOU shall be effective unless it is in writing and duly signed by both parties.

11. **FORCE MAJEURE:** Neither party shall be liable for any delay in or failure of discharging respective obligations under this MOU caused by occurrence beyond the control of KLE Ayurveda hospital or RCC as the case may be, including but not limited to fires, floods, explosions, power shortage, failure/breakdown of UPS/DG set/computer, acts of GOD, hostility, acts of public enemy wars, insurrections, riots, strikes, lockouts, sabotage. Either parties shall promptly but not later than 10 days of the commencement there of notify the other in writing of such contingency and prove that such is beyond the control and affects the implementation of this MOU adversely and materially. If such contingency continues beyond 30 days both the parties, agree to discuss and agree upon an equitable solution.

12. **ARBITRATION:** For any interpretation of clauses in this MOU or in case of any dispute during implementation, such matter will be jointly discussed by representative of KLE Ayurveda hospital and RCC. In case of disagreement, the matter would be referred to the International Centre for Alternative Dispute Resolution (ICADR, an autonoMoUs organization

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working under the aegis of the Ministry of Law and Justice, Govt. of India) New Delhi-110 070. ICADR decision would be binding on both parties.

IN WITNESS, WHERE OF, the parties have executed this MOU as of the date first above written

SIGNED AND DELIVERED BY	**SIGNED AND DELIVERED BY**
Registrar KLE University	**RCC**
through its Authorized Signatory	**through its Authorized Signatory**
Signature	**Signature** Yogesh Bendale
Name of person signing MOU	**Dr Yogesh Bendale**
Designation	**Chairman and MD (RBPL)**
in the presence, of	in the presence, of Dr. Anand Patil
in the presence, of Sivadhar (Dr. Vedantam Grividhar)	in the presence, of Dr. Neha Mali

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INSTITUTIONAL ETHICS COMMITTEE
KLE University's Shri B. M. KankanawadiAyurvedMahavidyalaya&
KLE Ayurveda Hospital, Shahapur, Belgaum

COMMUNICATION OF DECISION OF THE INSTITUTIONAL ETHICS COMMITTEE (IEC)

Protocol No: BMK/17/BSP /01

Protocol Title: "A prospective, open labelled, pilot, group study to evaluate efficacy, safety and bio availability of oral Arsenic Trioxide prepared by Ayurvedic method (Somal) in patients of solid tumours"
Principal Investigators/Co-investigators: Dr. B. S Prasad. Dr Santosh Patil
Name & Address of Institution: KLE University's Shri B. M. KankanawadiAyurveda Mahavidyalaya&KLE Ayurveda Hospital, Shahapur, Belgaum
☐ New Review ☑ Revised Review ☐ Expedited Review
Date of Review (DD/MM/YY): 5.4.2018 **Date of previous review, if revised application: 21.07.2017** **Name of the Reviewers who attended the meeting:** Dr. SupriyaBhalerao, Dr. RajashreeKamat, Dr. Pradeep Shinde, Dr Aziz Arbar, Mrs. Arati S Balikai, Mrs. Sarita S. Shirodkar, Dr. Basavaraj R Tubaki,
Decision of the the Ethics Committee: **Recommended** ☐ **Recommended with suggestions** ☑ **Revision** ☐ **Rejected** ☐

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Suggestions/ Clarifications / Reasons/ Remarks:
1. Minor revisions to the protocol have been approved by IEC
Recommended for a period of : One Year

Please note *

- Inform EC immediately in case of any Adverse Events and Serious Adverse Events
- Inform EC in case of any change of study procedure, site and investigator
- This permission is only for period mentioned above
- Annual report to be submitted to EC
- The study has to be conducted as per approved protocol. Any amendments in the Protocol/ICF/CRF has to be approved from IEC before implementation
- Members of EC have right to monitor the trial with prior intimation
- The status of the study (Completed/Ongoing/Terminated) should be reported annually
- It is mandatory to obtain renewal of approval and apply for the same at the end of 11 months
- The renewal of approval is subjected to submission of annual report. If the above application is not received within specified period then the permission to renew the project may lapse

Dr. Basavaraj R Tubaki
(Member Secretary)

Dr Supriya Bhalerao
(Chairperson)

Page 2 of 2

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महाराष्ट्र MAHARASHTRA ◑ 2019 ◑ AS 021211

अनु.क्र. 20482 दि. 30 JUL 2019
मु.शु.रक्कम- 500/-
दस्ताचा प्रकार- Agreement
दस्त नोंदणी करण्यास लावलेला वेळ- तास/मिनिटे
पक्षकाराचे नाव- KAHER's University, Kaher's Shri B M Kankanwadi Ayurved Mahavishwavidyalaya
पत्ता- K.Ayurved Hospital, Belgavi 590003
दुसऱ्या पक्षकाराचे नाव- Rasagani Biologics Pvt Ltd
हस्ते व्यवहाराचे नाव व पत्ता- Avinash Gulavani, Singhgad Rd Pune
नितीन एम. कांबी (परवाना न.२२०१०५५) शॉप नं.२१, केदार एम्पायर, वडगाव रोड, पुणे-३८ फोन-२५४६३४८४
हस्ते/मुद्रांक विकत घेणाराची सही

दुय्यम निबंधक अधिकारी हवेली पुणे
25 JUL 2019
प्रधान मुद्रांक लिपीक दुय्यम निबंधक हवेली पुणे क्रमांक

CLINICAL TRIAL AGREEMENT

This Clinical Trial Agreement (the Agreement) is entered on the 01 day of August 2019 between **Dr. B. S. Prasad** ("Investigator"), at KAHER collage of Ayurveda having an address at **KAHER Collage of Ayurveda and Hospital ,Belgaum** and **Rasayani Biologics Pvt. Ltd. (RBPL)**; with a registered office at **Pune, India.**

01-08-2019

Co-Investigator
Dr Santosh Patil
1-8-19

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"Investigator", "Institution", and "RBPL" are hereinafter collectively referred to as "Parties" and individually as a "Party".

PROTOCOL NUMBER:	RBPL/Somal- NTAX-44/001
PROTOCOL TITLE:	A prospective, open label, pilot, study to evaluate efficacy, safety and bio-availability of oral Arsenic compound prepared by Ayurvedic method (Somal- NTAX-44) in patients with solid tumors.
STUDY PRODUCT:	NTAX-44
Sponsor	Rasayani Biologics Pvt. Ltd. Pune.
INVESTIGATOR	Dr. B S Prasad
INSTITUTION/SITE:	Dept. of Shalakya Tantra, KAHER collage of Ayurved and Hospital Belgaum (India)- 590003

WHEREAS, RBPL (hereinafter referred to as Sponsor), wishes to engage the Investigator to carry out Sponsor designated clinical study set out and described in protocol RBPL/Somal- NTAX-44/001 and the Investigator is able and willing to conduct a clinical trial (the "Study"), in accordance with the above-referenced Protocol (the "Protocol" and any subsequent amendments thereto) on the terms and conditions set forth in this Agreement. Sponsor wishes to contract with the Investigator for conducting the Study at the Institution.

WHEREAS, the Investigator is willing to conduct the Study in accordance with the above-referenced Protocol and any subsequent amendments thereto and Sponsor requests the Investigator to undertake such Study;

NOW THEREFORE, the parties have agreed as follows:

A. Sponsor has requested the investigator to conduct the portion of the Clinical Study (referred to hereinafter as the "Study) that is to be conducted at the Institution under the supervision and direction of the Investigator pursuant to this Agreement. The Investigator and Institution agree to ensure that all associates, employees assisting in the conduct of the Study and other study team members will be bound by the terms of this Agreement. The Investigator and Institution shall conduct the Study in accordance with: (a) the Protocol; (b) the terms of this Agreement, (c) the Financial Agreement attached as Appendix A; and any other the attachments hereto, which are all incorporated by reference herein (the "Agreement"), (d) the International Conference on Harmonization ('ICH') guidelines for Good Clinical Practices ('GCP'), Ethical Guidelines for Biomedical Research on Human Subjects as prescribed by the Indian Council of Medical Research 2000 and all applicable laws and regulations and approval of the Ethics Committee ('EC') of the Institution. The Investigator hereby warrants that he has the experience, capability and resources, including, but not limited to, sufficient personnel and equipment to perform the Study in a professional and competent manner, and in strict adherence to the Protocol.

01-08-2019

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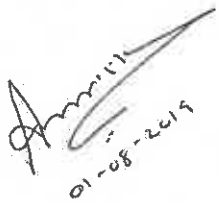
B. The Study will be conducted at the Institution under the direction of the Investigator identified above. The Investigator and Institution will be responsible for performing the Study and for direct supervision of any individual performing any portion of the Study at the Institution. In the event the Investigator becomes unwilling or unable to perform the duties required for the Study conducted under this Agreement, the Institution and Sponsor shall attempt to agree on a mutually agreeable replacement. In the event a mutually acceptable replacement is not available, then the Agreement may be terminated by Sponsor hereto in accordance with Section 10 of this Agreement.

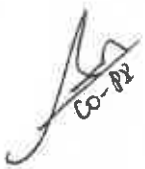
C. In consideration of conducting the Study hereunder, Sponsor shall pay the Payee for the conduct of the Study, in accordance with the budget and payment schedule attached as Appendix A to this Agreement, with the last payment being made after the Investigator and Institution complete all obligations hereunder, including the return of any Confidential Information as defined herein, and after Sponsor receives verification that all completed case report forms (CRF's) have been completed and data queries have been entered and resolved

D. In the event that the Study does not start or is terminated prematurely by the Sponsor, Investigator/Institution shall be entitled reimbursement for all reasonable fees and expenses incurred by the Investigator/Institution up to the effective date of termination of the Study on the production of bills to Sponsor. The Investigator/Institution will not be paid for Study subjects who do not complete the Study unless the Study is terminated in accordance with Section 10.In this case the sponsor will pay the complete Institutional charges i.e 15 % of the total budget as mentioned in Appendix A.

E. This Agreement will become effective on the date on which it is signed by the parties.

F. Investigator's signature below evidences Investigator's agreement that, prior to commencement of the Study, he/she shall read and ensure that he/she understands all information in the Protocol and the Investigator's Brochure, including the potential risks and side effects of the Study Product, and understands the Applicable Laws and Requirements.





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TERMS AND CONDITIONS

1. **Conduct of the Study.**

1.1 **Before Commencement of Study.** Before the Study commences, the Investigator shall make necessary filings and obtain all necessary authorizations, approvals, favourable opinions and other regulatory documentation required by the Protocol and "Applicable Laws and Requirements" (defined below), including:

a. Written approval or favourable opinion from all relevant ethics committees or Institutional Review Boards (the "Ethics Committee") regarding the conduct of the Study, the terms of the Protocol (including the informed consent template), recruitment procedures, and the other matters designated for their opinion under the Protocol or Applicable Laws and Requirements. Sponsor will assist the Investigator in making applications to the Ethics Committee by providing relevant information and documentation.

b. In addition, before participating in the Study, the Investigator shall sign and deliver to Sponsor an Investigator's Study Undertaking in accordance with Appendix VII to Schedule Y to Drugs and Cosmetics Rules, 1945, and such other applicable documents as may be required from Investigator pursuant to Applicable Laws and Requirements, and Institution and Investigator shall cause any co-investigators or sub-investigators to timely submit such documentation to Sponsor.

c. The Investigator shall also, prior to commencement of the Study, provide to RBPL a copy of all (i) requests for review, requests for authorization, and requests for opinion, (ii) approvals, authorizations, favourable opinions and any other opinions given by any of the Ethics Committee, and (iii) any other documentation filed with and/or received from any Ethics Committee or Regulatory Authority related to the Study.

d. After the conditions precedent set forth in this Section 1.1 are satisfied, the Institution and Investigator shall commence the Study, and shall comply with the conditions attached to the authorizations/approvals.

e. The Investigator will review and understand the information in the Investigator's Brochure/ Package Insert , shall ensure that all informed consent requirements as well as the procedures described in the Protocol in relation to each Study patient are met. Investigator will complete a CRF for each Study patient in accordance with the procedure set out in the Protocol. Investigator will review and sign each of the CRF's to confirm that they accurately reflect the data collected during the Study.

f. Upon completion of the Study, investigator shall inform the Institution, Ethics Committee with the summary of Study report.

ATTESTED

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1.2 **Site Visits.** The Institution and the Investigator shall permit Sponsors representatives to visit the Study Site during normal business hours, with reasonable advance notice, to review personnel procedures, and facilities; to discuss with Investigator the general obligations regarding the Study to review Investigator's Study file and the forms used for data collection for completeness and adherence to the Protocol; and to ensure compliance with this Agreement and all Applicable Laws and Requirements. The Investigator will promptly and fully produce all data, records and information relating to the Study, to the Sponsor and their representatives and shall assist them in resolving any questions and in performing audits or reviews of original subject records, reports or data sources

1.3 **Study Product.** (a) Upon the receipt by the Sponsor of the written approval of the Institution's Ethic Committee Sponsor shall provide the Investigator, at no charge, with such quantities of the Study Drug as may be required for the Study. The Investigator and Institution shall have no liability for any failure to fulfill its obligations as a result of unavailability of the Study Drug. Upon completion or termination of the Study, Sponsor may retrieve all unused Study Drug and Study materials (such as unused laboratory kits) and all Confidential Information (as defined below). The Investigator and Institution will keep full and accurate records of who dispenses the Study Drugs, the quantity dispensed and the quantity returned. The Investigator and Institution shall use the Study Drug being tested in connection with the Study, solely for the purpose of properly completing the Study and shall maintain all Study Drug and Study materials provided by Sponsor in a locked, secured area at all times.

(b) The Investigator shall be primarily responsible for the Study Product's accountability and will keep full and accurate records of the use and disposition of the Study Product, including the delivery of the Study Product to the Investigator's Site, the inventory at the Site, who dispenses the Study Product the quantity dispensed, and the quantity returned to the Sponsor or disposed

(c) Institution and Investigator shall comply with all Applicable Laws and Requirements governing the disposition or destruction of Study Product and with instructions from Sponsor.

1.4 **Adverse Events.** The Investigator shall report all adverse events, adverse reactions, product problems and any other reportable events or product use errors to the Sponsor immediately and within the timelines defined in the Protocol, and to report the same to the Ethics Committee in accordance with the Protocol and Applicable Laws and Requirements, and shall otherwise comply with all Applicable Laws and Requirements in connection therewith. Sponsor shall ensure that an up-to-date Investigator's Brochure on the Study Product is available for dissemination to the Ethics Committee, as well as subsequent modifications, if any, to the Subject Information Sheet and informed consent template

01-08-2019

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1.5 **New findings.** Sponsor will promptly report to the investigator any new findings that could affect the safety of participants and the willingness of participants to continue participation influence the conduct of the study or alter the IRB's approval to continue the study. Those findings that could affect the safety or medical care of the participants will be communicated to the participants by the Investigator. The investigator will also inform the participant when medical care is needed for an illness of which the investigator becomes aware.

2. **Recruitment.** Subject to all necessary approvals being obtained, the Investigator shall be responsible for the recruitment of Research Subjects in the Study. The Investigator shall use the Investigator's best efforts to ensure that Research Subjects fulfilling the Protocol criteria are recruited Investigator shall ensure the unbiased selection of an adequate number of suitable subjects according to the Protocol, and shall use best efforts to enrol the subjects specified by Sponsor from time to time Investigator acknowledges that Sponsor reserve the right to limit entry or enrolment of subjects at any time on written notice to Investigator. Investigator shall obtain the written approval of the Ethics Committee and Sponsor to the text of any communication soliciting subjects for the Study before placement, including, but not limited to, newspaper and radio advertisements, direct mail pieces, Internet advertisements or communications, and newsletters, which communications must comply with Applicable Laws and Regulations.

3. **Enrolment; Notices; Informed Consent; Authorization:**

Prior to enrolling a Research Subject in the Study, Investigator shall obtain (a) the Research Subject s informed consent, as evidenced by a signed informed consent document evidencing the informed consent of Research Subjects for participation in the Study, in the form approved by the relevant Ethics Committee; (b) an Authorization (as defined and described below); and (c) such other consents as may be required by the Protocol or Applicable Laws and Requirements.

Institution and Investigator shall adhere to the principles of medical confidentiality and shall comply with all Applicable Laws and Requirements related to the personal data of Research Subjects, including data privacy or data protection laws of the country in which the data originated. Investigator shall obtain from each Research Subject and provide to Sponsor a written consent and authorization valid under Applicable Laws and Requirements (each, an "Authorization") for the access, use, processing, storing, disclosure and transfer of the Research Subject's personal data by and to (a) Institution, Investigator, and their study team, (b) persons monitoring the Study and/or the Clinical Study or conducting an independent valuation of the Study and/or the Clinical Study, (c) the representatives of the Ethics Committee, (d) the Regulatory Authorities, and (e) Sponsor and Central Lab and their representatives and agents, including third parties directly or indirectly performing services for Sponsor related to the Study and/or the Clinical Study

01-05-2015

Co-Investigator

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4. **Confidential and Proprietary Information.** All information (including, but not limited to documents, descriptions, data, CRFs, photographs, videos and instructions), and materials (including but not limited to, the Study Product), provided to the Investigator and Institution by Sponsor or their agents (whether verbal, written or electronic), and all data, reports and information relating to the Study Product, the Study or its progress (hereinafter, the "Confidential Information") shall be the property of Sponsor. The Investigator and Institution will undertake to keep in strict confidence and not at any time to use other than in the Study or to disclose or permit to be disclosed to any third party the data and results of the Study and any information provided directly or indirectly by the Sponsor or Sponsors Representatives under this Agreement. The Investigator and Institution shall keep the Confidential Information strictly confidential and shall disclose it only to its employees involved in conducting the Study on a need-to-know basis. The Investigator and Institution shall ensure that the immediate members of the staff and any co-investigator who have access to Confidential Information are informed of its confidential nature and agree in writing to keep it strictly Confidential in accordance with the provisions of this Section 4. The obligations of non-disclosure stated in this Section shall be for a minimum period of ten (10) years after disclosure of said Confidential Information to Investigator and/or Institution under consideration for the provisions of sub-section 4 (a) – (f) inclusive, and these confidentiality obligations shall continue after completion of the Study, but shall not apply to Confidential Information to the extent that it: a) is or becomes publicly available through no fault of the Investigator and Institution; b) is disclosed to the Investigator by a third party not subject to any obligation of confidence; c) must be disclosed to ECs or applicable Regulatory Authorities; d) must be included in any Study subject's ICF; e) is published in accordance with Section 7 herein; or f) is required to be disclosed by applicable law.

5. **Intellectual Property Rights** - All intellectual property rights existing prior to the date of this Agreement will belong to the Party that owned such rights immediately prior to the date of this Agreement. Neither Party will gain by virtue of this Agreement any rights in or ownership of copyrights, patents, trade secrets, trademarks or any other intellectual property rights owned by the other party. The Investigator and Institution hereby agree that the Sponsor shall own all intellectual property rights arising out of the Study and related to the Study Drug, including any rights with respect to any discoveries, inventions, whether patentable or otherwise and which relates to the materials and arising as a result of the Study. The Investigator and Institution will, at Sponsor's expense, execute any documents and give any testimony necessary for Sponsor to effect the transfer of the title of such property, obtain patents in any country or to otherwise protect Sponsor's interests in such inventions. The Investigator and Institution shall have exclusive ownership of any inventions or discoveries conceived by the Investigator and Institution during the course of the study that are wholly unrelated to the Study Drug and Protocol and do not arise in whole or in part from the Study or any Confidential Information, but the Investigator and Institution shall offer the Sponsor the right of first refusal as to any sales or licenses of such inventions. The Investigator and Institution agree to comply with any applicable data privacy or data protection legislation of the country in which the data originated.

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6. **Study Records.**

6.1 The Investigator shall prepare, maintain and retain complete, accurate, and legible source documents, regulatory documents, and other written records, accounts, notes, reports, and data relating to the Study (collectively, "Records"), including CRFs and including all documentation and records concerning the Study Site, the solicitation, screening, evaluation, enrollment and testing of subjects (including the relevant portions of other pertinent records concerning such subjects, all queries raised by the subject during the informed consent administration and the responses provided); the procedures, tests and other activities performed during the Study; results and interpretations, including statistical analyses, if required; and all financial transactions related to the Study. Further, the Investigator shall ensure that the data reported on the CRFs that is derived from source documents is consistent with the source documents, and discrepancies, if any, shall be explained. All original CRFs shall be made available to **Sponsor** in a timely manner throughout the performance of the Study. CRFs shall identify the Research Subjects by randomization number and/or screening number assigned to the subjects rather than by the subjects' name(s), personal identification number(s) and / or addresses

The Investigator shall retain the Records of the Study, including either the original or a copy of all volunteer consent forms, for the longer of:

(i) two (2) years after the Investigator is notified by Sponsor that the clinical development of the Study Product has been formally discontinued; and

(ii) as may be required under the applicable Indian laws and regulations.

6.2 Investigator shall maintain and store all records and reports related to the study. In no event shall Investigator remove any Records from the Study Site or destroy any Records without the prior written consent of Sponsor. Upon expiration of the applicable retention period, Sponsor shall, upon Institution or Investigator's request, direct that such Records be delivered to Sponsor or Sponsor's representative, be destroyed, or be retained by Institution/Investigator, and Institution/Investigator shall comply with Sponsor's directions.

7. **Publication.** The results of the Study including all obtained data will be the property of the Sponsor. The Investigator and Institution should not publish or communicate the data in public without written authorisation by Sponsor. Unpublished data should not be disclosed to any third party by the Investigator and Institution without the written approval of the Sponsor. The Investigator and /or Institution may have access to the Study data resulting solely from his/her participation in the Study for purely scientific or educational purposes, but unless previously explicitly permitted in writing by Sponsor he/she may not use the data for any commercial purposes.

01-08-2015

Co Investigator

ATTESTED

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Investigator may publish or otherwise disclose the results of the Study provided that Investigator provides a copy to Sponsor, at least sixty (60) days prior to disclosure or submission to any third party, for review and comment. Within this sixty (60) days period, Sponsor shall review the proposed publication or release to determine whether it contains Confidential Information (as described in Section 4), whether Sponsor desires to file patent applications on subject matter contained in the proposed publication or release or to ensure the accuracy of the information contained in the publication or release. Upon receiving any notification from Sponsor requesting deletion of Confidential Information requesting correction of inaccuracies, or requesting a delay in publication to allow the filing of patient applications before publication or release, Investigator shall take the requested action; however, any delay in publication shall not exceed one hundred and twenty (120) days after Investigator takes the requested action.

8. Subject Injury Reimbursement

8.1 Subject to Investigator and Institution's indemnification obligations under Section 11.2 if a properly enrolled Research Subject suffers a "Research Related Injury" as a direct result of taking part in the Study, Sponsor will pay or provide reimbursement for injury or death with the actual and reasonable costs of medical treatment reasonably required to treat such injury or illness, if all of the following are true: (a) the injury or illness resulted directly from the Research Subject receiving the Study Product being evaluated in the Study or from a properly performed procedure required by the Protocol or injury or death arising thereof; (b) the Study Product was properly administered to Research Subject in compliance with the Protocol and this Agreement; (c) the Research Subject followed all of the instructions that the Investigator and other members of the Study team gave the Study subject, and (d) the costs are not covered by the Research Subject's insurance or by any other third-party payer. For purposes of this Agreement, the term "Research Related Injury" means physical injury or ill effect, disability whether temporary or permanent and serious or otherwise caused by the Products or procedures prescribed in the Protocols, which are different from the medical management the Research Subject would have received if he had not participated in the studies.

8.2 Except as set out in Section 8.1 above or as otherwise required by Applicable Laws and Requirements, Sponsor shall have no obligation to provide Research Subjects with any other money or payment for any injury or illness, including any payment for any lost wages, disability or discomfort that Research Subjects may experience as a result of taking part in the Study. In addition, Sponsor will not be responsible for paying the cost of medical care for treatment of a Study subject's underlying conditions, or for any complication of a Study subject's underlying condition or new illness that may develop during the Study, if it is not directly caused by taking part in the Study

01-08-2019

ATTESTED

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9. Inspection and Debarment.

9.1 Investigator and Institution shall cooperate with any government inspection or audit of the Study site or records. The Investigator and Institution agree to communicate in writing or contact by telephone or fax Sponsor prior to any communication or meeting with any Regulatory Authority relating to the Study, and the Investigator and Institution would provide the Regulatory Authority only with information approved for disclosure by the Sponsor. The Investigator and Institution agree, upon reasonable notice, to disclose, from time to time, for inspection/audit by representatives of the Sponsor and/or national or international Regulatory Authorities, all such report forms and further documentation and information used and/or generated in the Study. The Investigator and Institution shall immediately notify Sponsor of, and provide Sponsor copies of, any inquiries, correspondence or communications to or from any governmental or Regulatory Authority relating to the Study, including, but not limited to, requests for inspection of the Institution's facilities, and the Investigator and Institution shall permit Sponsor to attend any such inspections. The Investigator and Institution will make reasonable efforts to separate, and not disclose, all confidential materials that are not required to be disclosed during such inspections, except as required by law. The Investigator and Institution shall also arrange for access by such individuals to source data and shall be responsible for obtaining the informed consent of Study subjects to such disclosure of personal medical data and records, if required by law, and if not expressly granted by the subject in the signed ICF.

9.2 The Investigator and / or Institution shall permit the representatives of Sponsors to visit the premises on which the Study is being conducted and arrange/ grant access to laboratories and facilities used in connection with the Study, at periodic intervals at a mutually agreeable time

9.3 The Investigator and Institution shall permit the Sponsor to inspect and audit the Institution. The Investigator and Institution shall be responsible for maintaining essential Study documents for the time and in the manner specified by current ICH-GCP guidelines, local laws, and Sponsor requirements and shall take measures to prevent accidental or premature destruction of these documents. In the event the Investigator leaves an Institution or otherwise changes addresses, the Investigator and Institution shall promptly notify the same to Sponsor.

9.4 The Investigator and Institution represents and warrant that neither the Investigator nor the Institution or nor any of the employees, agents or other persons performing the Study under the Investigator's direction, has been debarred, disqualified or banned from conducting clinical trials or is under investigation by any Regulatory Authority for debarment or any similar regulatory action in any country, and the Investigator or Institution shall notify Sponsor immediately if any such investigation, disqualification, debarment or ban occurs.

ATTESTED

Dr. V.A.Kothiwale
Registrar
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(Deemed-to-be-University u/s 3 of the UGC Act,1956)
Belagavi-590 010,Karnataka

9.5 Sponsor on its part will allow the investigators and / or representatives of the institution to supervise the analysis of blood samples collected during the study for the determination of concentration of the investigational product in those samples at their facility.

10. Study Term and Termination.

10.1 This Agreement shall be effective upon the date it is signed by all the parties and shall continue in effect till the completion of the Study as mentioned in the Protocol, unless terminated earlier by the parties as given below:

a. Sponsor, may terminate this Agreement with prior written notice of 30 days to the Investigator/ Institution for reasons including but not limited to any of the following occurrences:
   i) if patient enrolment, as defined in Section 2, has not been completed within the scheduled period;
   ii) 45 days after shipment of the Study Drug or material, no patients have been enrolled or the Investigator recruits no patients or recruits such a low number of patients that it can be assumed that the agreed number of patients will not be reached during the planned recruitment phase;
   iii) Sponsor terminates the Study or the Study Drug or the indication is discontinued.
   iv) It is proved that the dosage used for the Study no longer seems to be justified;
   v) A regulatory authority or other pertinent institution decides to terminate the Study in this Institution or as a whole;
   vi) The Investigator/ Institution fail to adhere to the conditions of the Protocol and the requirement to complete CRF data according to the Guidelines for Good Clinical Practice.

b. Should the Investigator/Institution recognise, with reasonable discretion, that continuation of the Study is no longer medically justified, due to (i) unexpected results (ii) the severity or prevalence of serious adverse effects or (iii) the efficacy of the treatment with Study Drug appears to be insufficient; then he/ she will promptly notify Sponsor as well as the ethics committee in writing. Should Sponsor or the ethics committee agree that continuation is not justifiable; the Investigator/Institution may arrange immediate termination of the Study.

c. Whichever party terminates the Study early shall provide the other parties with a written statement of its reasons for doing so. Sponsor will notify Regulatory authorities as appropriate of early termination, except that the Investigator will notify the Ethics committee.

07-05-2019

ATTESTED

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Belagavi-590 010,Karnataka

10.2 Effect of Termination Upon receipt of notice of termination, the Investigator shall immediately cease any patient recruitment, complete all outstanding Case Report Forms and return to Sponsor all documents/equipment (if any) provided by Sponsor under this Agreement and following the specified termination procedures, ensure that any required subject follow-up procedures are completed, and make all reasonable efforts to minimize further costs. In the event of early termination, Sponsor shall make a final payment for visits or milestones properly performed pursuant to this Agreement in the amounts specified in the Payment Schedule (Annexure A), provided however that ten percent (10%) of this final payment will be withheld until final acceptance by Sponsor of all completed CRFs and all data clarifications issued and satisfaction of all other applicable conditions set forth in this Agreement.

10.3 Sponsor shall not be responsible to the Investigator or the Institution for any lost profits, lost opportunities, or other consequential damages arising out of this Agreement. If a material breach of this Agreement appears to have occurred and termination may be required then, subject to subject safety, Sponsor may suspend performance of all or part of this Agreement, including but not limited to, subject enrollment.

11. Indemnification; Claims and Disclaimers

11.1 Sponsor shall indemnify and hold harmless Investigator and Institution and its director, officers, employees, subcontractors, agents (collectively, hereinafter "**Institution Indemnitees**") from any loss, liabilities, damage or other reasonable expenses (hereinafter "Claims"), resulting from any third party claims, actions, or proceedings, investigations or litigation brought against any Institution Indemnitees arising out of the use of the Study drug or procedures required by the Protocol in strict compliance with the Protocol; provided, however, that Sponsor will not indemnify or hold harmless the Institution Indemnities for any Liabilities arising from any injuries or damages that are a result of:

(i) the negligence or intentional misconduct of any of the Institution Indemnitees and/or
(ii) any activities conducted contrary to the provisions of the Protocol or outside the scope of the Protocol; or information supplied by Sponsor and/or generally accepted medical standards and the applicable SOPs, and/or
(iii) any negligence, omission, or willful misconduct by any Institution Indemnitees in the performance of their obligations under this Agreement and/or
(iv) failure to have complied with all dosage and other specifications, directives and recommendations furnished by the Sponsor for the use and administration of the Study Drug and/or
(v) all applicable laws, rules, and regulations

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However, Sponsor's indemnification obligations are subject to the following conditions:

a. The Research Subjects involved gave an adequate written informed consent and was provided prompt diagnosis and appropriate medical care following the occurrence of the injury;
b. The Sponsor receives notice of the applicable, the diagnosis, the care initiated and the care anticipated to be necessary and all appropriate follow-up reports; and
c. Institution Indemnities reasonably cooperates with Sponsor and its legal representatives in the defense of any claim, demand, action or other proceeding covered by this Agreement; and
d. Permits Sponsor to select and retain counsel to represent the Institution Indemnities.
e.. The indemnification obligations above shall not apply to amounts paid in settlement of any claim, demand, action or other proceeding if such settlement is effected without the consent of the Sponsor

Sponsor's indemnification obligations do not apply to any complication of an underlying illness or any other injury that any Research Subjects may experience during the course of the studies that is not directly related to the Study Drug.

11.2 Investigator and Institution shall indemnify, defend, and hold harmless Sponsor and each of their respective affiliates, directors, officers, employees, contractors, and agents from and against any loss claim or demand arising from the following: (i) injuries or damages resulting from the negligent or willful misconduct of the Investigator and Institution or any of their respective affiliates, directors, officers, employees, contractors, and agents, including any co-investigators or sub-investigators performing the Study; or the failure of Institution and/or Investigator or any of their employees, contractors, and agents, including any co-investigators or sub-investigators, to comply with the Protocol or written instructions of Sponsor or any Applicable Laws and Requirements; or (ii) any breach by Institution or Investigator of any of their respective obligations under this Agreement, including but not limited to any failure to comply with the Protocol or any Applicable Laws and Requirements or (iii) any case in which the Investigator fails to obtain an informed consent form in compliance with the terms of this Agreement or otherwise fails to comply with local or national laws or regulations provided:

Each Party's obligations under this Agreement are further conditioned upon the indemnified Party giving the Indemnifying Party timely written notice and assistance in the defense of any claim, proceeding or investigation; provided however, that failure of the indemnified Party to give such notice shall not limit the indemnified Party's right to indemnification except in such case where such failure materially and adversely affects the indemnifying Party's ability to defend against such claim, proceeding or investigation. Neither Party will enter into any settlement agreement that attributes fault nor negligence to the other Party, requires any payment by the other Party, or restricts the future actions or activities of the other Party, without the other Party's prior written consent

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11.3 The Investigator and Institution shall promptly notify Sponsor in writing of any claim of illness or injury actually or allegedly due to an adverse reaction to the Study Product and allow Sponsor to handle such claim (including settlement negotiations), and shall cooperate fully with Sponsor in its handling of the claim.

11.4 Institution and investigator acknowledge that the study product is experimental in nature, is not for commercial use, and is provided "as is" without any warranty, representation or undertaking whatsoever, express or implied, including, without limitation, any warranty of merchantability, fitness for a particular purpose, or non-infringement.

12. **Financial Disclosure.** The Investigators and the Institute should disclose any financial interest with the Sponsor which may cause Conflict of Interest and can introduce Bias in conduct of the study. Such conflict of Interest if any should be disclosed and notified to the Institutional Ethics committee and the sponsor.

13. **Shipping of Dangerous Goods and Infectious Materials.** The handling, packaging and shipment of dangerous goods and infectious materials (including infectious specimens) are subject to local and national laws and regulations

14. **Publicity.**

14.1 **Solicitation of subject:** Sponsor and Institutional Review Board shall approve in writing, the text of any communication soliciting subjects for the Study before placement, including, but not limited to newspaper or radio advertisements, direct mail, internet advertisements or communications and newsletters. Such communication must comply with applicable laws and guidelines.

14.2 **Press Releases:** Sponsor shall approve, in writing, press statements by Investigator and Institution regarding the Study or the Study Drug before the statements is released.

14.3 **Enquiries from media and financial analysts:** During and after the Study, the Investigator and Institution may receive enquiries from reporters or financial analysts. Investigator and Institution confer with Sponsor / RBPL authorised signatory to this Agreement named below or other named person in the same position of employment at that time at Sponsor before responding to such enquiries.

14.4 **Use of Name.** Investigator and /or Institution or any of the Investigator and Institution's trained staff/employees, agents or other persons performing the Study under the Investigator's direction will not use Sponsor's name and/or Sponsor employees in any advertising or sales promotional material or in any publication without the prior written permission of Sponsor. Sponsor shall not use the Institutions name and the name of the Investigator or Institution employees in any sale's promotional material or in any publication without written permission from the Investigator and Institution.

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15. Additional Contractual Provisions.

15.1 In conducting the Study, the Investigator and Institution shall be an independent contractor and shall not be considered the partner, agent, employee, or representative of Sponsor and the Investigator and /or Institution has no authority to bind Sponsor to any contract or commitment unless specifically authorized to do so in writing. This Agreement, including these terms and conditions, constitutes the sole and complete agreement between the Parties and replaces all other written and oral agreements relating to the Study.

15.2 The following provisions shall survive the termination or expiration of this Agreement, Section 4 (Confidential and Proprietary Information); Section 6 (Study Records); Section 7 (/Publication), Section 8 (Subject Injury Reimbursement); Section 11 (Indemnification; Claims and Disclaimers) and Section 14 (Publicity/Use of Names)

15.3 Amendments No amendments or modifications to this Agreement shall be valid unless in writing and signed by all the Parties. Failure to enforce any term of this Agreement shall not constitute a waiver of such term. If any part of this Agreement is found to be unenforceable, the rest of this Agreement will remain in effect. This Agreement shall be binding upon the Parties and their successors and assigns.

15.4 Restrictions on Assignment. This Agreement shall be binding upon the Parties and their permitted successors and assigns. The Investigator and Institution shall not assign or transfer any rights or obligations under this Agreement without the written consent of RBPL.

15.5 Conflict of interest. Investigator and Institution warrant and represent that the Investigator has no obligations, contractual or otherwise, that would conflict with its entering into this Agreement. Investigator and Institution further agree that subsequent to execution of this Agreement, the investigator and /or Institution will undertake no obligations that would conflict or interfere with its performance hereunder.

15.6 Notice. Any notices that either Party may be required to give the other shall be deemed to be duly given when mailed by certified or registered mail, postage prepaid, to the other Party at the addresses first given above or to such other addresses as the Parties may direct in writing. Any notice or other communication required or permitted under the Agreement shall be in writing and will be deemed given as of the date it is received by the receiving party.

15.7 Governing Language: Governing Law. The controlling language of this Agreement and all related documents, correspondence and notices shall be in English. This Agreement shall be governed by and construed in accordance with the laws of India without conflict of laws and principles

01-08-2019

ATTESTED

Dr. V.A.Kothiwale
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KLE Academy of Higher Education and Research,
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Belagavi-590 010,Karnataka

15.8 Arbitration. Any dispute, controversy or misunderstanding between the Parties arising out of or related to this Agreement or any breach thereof shall be mutually settled by the Parties between their authorized representatives within a period of thirty days. In case, the dispute is not settled within a period of thirty days by the authorized representatives, the same shall be submitted to arbitration in accordance with Arbitration and Conciliation Act, 1996. Parties shall appoint a sole arbitrator, mutually agreed by the Parties or panel of arbitrator as required thereto. The place of Arbitration shall be at Mumbai and the language shall be in English. Each party shall bear its own costs of the arbitration unless the arbitrator otherwise directs. Any award rendered by the arbitrators shall be in writing, shall be the final binding disposition on the merits, and shall not be appealable to any court in any jurisdiction. Judgment on an award rendered may be entered in any court of competent jurisdiction, or application may be made to any such court for a judicial acceptance of the award and an order of enforcement, as appropriate. The Parties waive any right they may enjoy under the law of any nation to apply to the courts of such nation for relief from the provisions of this Item or from any decision of the arbitrators. In the event a court of competent jurisdiction determines that this Agreement is invalid or unenforceable for any reason, this provision shall not be affected thereby and shall be given full effect without regard to the invalidity or unenforceability of the remainder of this Agreement. Notwithstanding anything herein seemingly to the contrary, any party may seek injunctive relief from a court of competent jurisdiction to prevent or limit damage to that party's intellectual property.

15.9 Counterparts. This Agreement may be executed in any number of counterparts, each of which shall be deemed an original and all of which shall constitute the same instrument. This Agreement shall be effective upon full execution by facsimile or original, and a facsimile signature shall be deemed to be and shall be as effective as an original signature.

01-08-2019

ATTESTED

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Belagavi-590 010,Karnataka

ACKNOWLEDGED AND AGREED BY RBPL:

By: _____ 01-05-2019

Name: Dr. Avinash Kadam

Title: Senior Scientist and Project Lead, RBPL, Pune

Date: 01-05-2019

ACKNOWLEDGED AND AGREED BY INVESTIGATOR:

By: _____

Name: Dr Santosh B Patil

Title: Co-Investigator

Date: 01-05-2019

ACKNOWLEDGED AND AGREED BY THE INSTITUTION:

By: _____

Name: Dr. B. S. Prasad, Principal

Title: Principal Investigator

Date: 1-05-2019

PRINCIPAL
Shri B. M. Kankanwadi
Ayurved Mahavidyalaya
A Constituent Unit of KAHER
Shahapur, BELAGAVI-03.

27/01/2020

Dr. Jogesh Bendale
Chairman and managing Director
Rasayani Biologics Pvt. Ltd.

ATTESTED

Dr. V.A.Kothiwale
Registrar
KLE Academy of Higher Education and Research,
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Belagavi-590 010,Karnataka

Appendix A

A.1. FINANCIAL SUMMARY

Sl.no	Particulars		Amount
01.	Protocol Development Charges	NIL	NIL
02.	Ethical Committee Charges	Paid	10,000/-
03.	Investigation Charges	NIL	1, 46,500/-
04.	Investigator Charges (PI and Co-I)	NIL	50,000/-
05.	Modern Consultant	1000/Patient	10,000/-
06.	JRF	5000/Month	60,000/-
07.	Hospital Bed Charges	(700/Day with food * 2 days 10 patients	14,000/-
08.	Wage Compensation	500/Visit * 6 visit * 10 Patients	30,000/-
09.	Consumables	NIL	5000/-
11.	Data handling	NIL	-10,000/-
12.	Stationary and miscellaneous	NIL	10,000/-
13.	Travel and Ambulance Chagares	1000/Patient	10,000/-
14.	Institutional Charges	NIL	
Total			3,85,500/-

01-04-2019

Dr Shwetha HS

ATTESTED

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Registrar
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Belagavi-590 010,Karnataka

A.2. PAYMENT SCHEDULE

- 1st installment 60 % of budget should be provided before initiation of the trial
- 2nd installment to complete 30 % of the total budget will be paid after recruitment of 50 % patient
- 3rd installment of further 10 % after completion of the trial at the time of report submission
- Any extra expenses (not mentioned in the budget) which occurs during the conduct of study will be reimbursed with 15 days of receiving the invoice, provided written approval for this from Rasayani Biologics has been taken for the extra expenses.

Note: RBPL will make payments for investigations and travel of screen failure patients. However RBPL shall reimburse Screen failure costs subject to maximum of 40% of the enrolled subjects at the site

Please note the following:

- Payments are calculated according to the above schedule's payable on confirmation by RBPL monitor.
- The investigator has to present statement on letterhead for claiming any above-mentioned payment under section A.1 (Financial Summary)
- Site is requested to keep the copy of the signed travel voucher (obtained from the subject) and hospital stay charges for audit purpose.
- EC fee, if any, would be paid by RBPL during the EC submission for the study
- Applicable TDS will be deducted by the sponsor for each payment.
- The Institute is required to produce the statement of utilization of funds before sending demand letter for next instalment.

01-08-2015

Co Investigator

ATTESTED

Dr. V.A.Kothiwale
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Belagavi-590 010,Karnataka

SHRI BM KANKANAWADI AYURVED MAHAVIDYALAYA
Post Graduate Studies & Research Centre
(Approved by Central Council of Indian Medicine, New Delhi & M/o AYUSH, GoI)
A Constituent Unit of
KLE ACADEMY OF HIGHER EDUCATION & RESEARCH
(DEEMED-TO-BE-UNIVERSITY)
(Re-Accredited 'A' Grade by NAAC (2nd Cycle) || Placed under Category 'A' by MHRD GoI)
First AYUSH Institution having NAAC & NABH Accreditation

IMPARTING AYURVEDA EDUCATION SINCE 1933

Certificate

Our institute had made an agreement with sponsor Rasayni for conducting clinical trial on title "Bioavailability of Arsenic Trioxide when administered orally in Cancer Patients"

Investigators: Dr B S Prasad, Dr Santosh Patil

Details of released Grant in rupees year wise

Details	2018-2019	2019-2020
Bioavailability of Arsenic Trioxide when administered orally in Cancer Patients	Rs.258170/-	Rs.725000/-

This is as per institutional audited financial reports

PRINCIPAL
Shri B. M. Kankanwadi
Ayurved Mahavidyalaya
A Constituent Unit of KAHER
Shahapur, BELAGAVI-03.

ATTESTED

Dr. V.A.Kothiwale
Registrar
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Belagavi-590 010,Karnataka

Gram Shikshana Charity Foundation
Administrative Office: 31, Morarji Nagar, Gokul Road,
HUBLI -580030 (Karnataka – India)
Cell: 91- 9986976289, 9483122979
Email: hombal@yahoo.com grascf99@yahoo.com

To,

Date: 18-04-2018

Dr, Mubashir B.A.,

HOD, Department of Public Health

JNMC Belagavi,

Dear Madam,

Greetings.

Sub : Sanction Letter.

With reference to our discussion on project : Canacare", I am pleased to inform you that, our trustees have agreed to associate with your department in implementing the above said project. The other terms are:

1) The project will be for one year from this date.

2) We will sanction Rs two (2) lakhs to execute this project.

3) You can select any medical colleges in Karnataka of your choice.

4) At the end of the project we request you to submit a Project completion report and most importantly a fund "UTILIZATION Certificate"

5) We will shortly send the payment of Rs two (2) lacks to JNMC.

We appreciate you for supporting this project

Warm Regards, thanking you

For GRAMA SHIKSHANA CHARITY FOUNDATION

Rxombal

(Ravindra Hombal)-Trustee

ATTESTED

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UTILIZATION CERTIFICATE

Program Name : A Joint venture project of JNMC – MPH Department and Grama Shikshana Charity Foundation Hubballi.

Project Title : A Concept Note on Promoting Cervical Breast and Oral Cancer Screening Programs (Preventive Oncology Program) at 6 Medical Colleges in Karnataka.

Sl. No.	Details	Amount
1	Previous year Balance (Opening Balance (OB),If any)	–
2	Grants Received (chq no : 192463 chq dtd :09.04.18)	2,00,000.00
	Actual utilized amount	**1,90,004.00**
	Overhead charges	**9,996.00**
	Remaining balance	**Nil**

Certified that out of Rs.2,00,000/- of Grants-in-aid sanctioned during the years 2018-19 in favor of J.N.Medical College, Belagavi for the study entitled A Concept Note on Promoting Cervical Breast and Oral Cancer Screening Programs under "A Joint venture Project of JNMC-MPH Department and Grama Shikshana Charity Foundation Hubballi" for conducting Cervical and Breast Cancer Screening camps in North Karnataka.

Certified that I have satisfied myself that the conditions on which the grant-in-aid was sanctioned have been fulfilled and that I have exercised the following checks to see that the money was actually utilized for the purpose for which it was sanctioned.

1. Bills and Vouchers

Signature and Address of Principal Investigator

Signature of the Head of Institution
Head of the Institute
PRINCIPAL
JAWAHARLAL NEHRU MEDICAL COLLEGE
BELAGAVI-590010

Signature with Seal
Account officer/
Authorized Auditor
FINANCE OFFICER
KLE Academy of Higher Education & Research, BELAGAVI

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