From

The Course Coordinator

Introduction to Clinical Research

Department of Community Medicine

Sree Balaji Medical College

Bharath Institute of Higher Education and Research,

Chennai

То

The Dean

Sree Balaji Medical College

Bharath institute of Higher Education Research,

Chennai

Sub: -Permission to conduct value- added course: Introduction to Clinical Research

Respected sir,

With reference to subject mentioned above, the Community Medicine proposes to conduct a value- added course titled: Introduction to Clinical Research

We kindly solicit your kind permission to commence the program.

Warm Regards,

SREE BALAJI MEDICAL COLLEGE & HOSPITAL

CHROMPET CHENNAI -600044

Date: 10/11/2018

R. No 276/ SBMCH/2018

CIRCULAR

Notification for Value added courses offered by the Department of Community

Medicine

The Department of Community Medicine of Sree Balaji Medical College is scheduled to offer a Value added Course on Introduction to Clinical Research from 11/7/2018 for a period of 3 weeks. Interested students can approach the Head of Community Medicine department and Course Coordinator, for registration and for further details on or before 10/31/2018.

Eligibility-MBBS STUDENTS

Course Coordinator

Copy to:

Dean office

Vice Principal

Medical Superintendent

AO College

HOD

INTRODUCTION TO CLINICAL RESEARCH

Course Outline: The drug and medical device development industry is experiencing a tremendous change globally. This change has geared momentum towards development of unique, newer and safer therapies and towards personalized medicinal drugs. The business models are advancing to the higher levels of niche busters and towards a coexistence of newer and blockbuster therapies used in the past. Due to the strengthening of economies in the BRIC countries i.e. Brazil, Russia, India & China, drug and device companies are focusing their research and development efforts in these regions particularly the research for clinical development of products i.e. Phase I to Phase IV clinical trials. Further, local pharmaceutical and biotech companies in these regions are also rapidly stepping up their work in Research and Development for developing promising new molecules as well as generics.

With the growth of the industry a number of clinical trial management organizations and business models have come into existence which include full-service Contract Research Organizations (CROs), early phase CROs, Site Management Organizations (SMOs), companies offering fewer but specialized services such as Clinical Data Management, Business Consulting, Knowledge Process Outsourcing (KPOs) etc. This growth has eventually amplified the demand for trained staff in the clinical research industry.

Clinical Research Course equips you with the knowledge and skills required for making a successful career in drug development and clinical trials. The program has been designed in a way so as to compliment your basic education and to provide you a platform to enter the pharmaceutical and biotech industry as a clinical research professional.

Course Duration: 30 hours

Course Coordinator: Associate Professor /Assistant professor of Medicine

Syllabus

Topic	Faculty	Rours	
		allotted	
GENERAL INTRODUCTION	Assistant Professor of Medicine	2 hours	
EPIDEMIOLOGY &	Associate Professor of Medicine	2 hours	
EVIDENCE BASED MEDICINE			
PHARMACEUTICAL	Assistant Professor of Medicine	2 hours	
MEDICINE			
THERAPEUTIC AREAS	Associate Professor of Medicine	2 hours	
ETHICS IN CLINICAL	Assistant Professor of Medicine	2 hours	
RESEARCH			

ROLES AND	Associate Professor of Medicine	2 hours
RESPONSIBILITIES		
CLINICAL TRIAL	Assistant Professor of Medicine	2 hours
PREPARATION		
ESSENTIAL DOCUMENTS	Associate Professor of Medicine	2 hours
AND REGULATORY		
SUBMISSION		
STUDY START-UP, CLINICAL	Assistant Professor of Medicine	2 hours
TRIALS MONITORING		
COMPLIANCE AND AUDITS	Associate Professor of Medicine	2 hours
DATA MANAGEMENT AND	Assistant Professor of Medicine	2 hours
BIOSTATISTICS		
REGULATORY AFFAIRS IN	Associate Professor of Medicine	2 hours
CLINICAL RESEARCH		
FINANCIAL MANAGEMENT	Assistant Professor of Medicine	2 hours
OF CLINICAL TRIALS		
Written test	Associate Professor of Medicine	2 hours



Bharath Institute of Higher Education and Research Sree Balaji Medical College & Hospital



CERTIFICATE

Balaji Medical College & Hospital, Chennai held during 11/7/2018. course on Introduction to Clinical Research conducted by Community Medicine at Sree This is to certify that Mr./Ms. CHINMAYEE PANIGRAHI has completed the value added

Dr.P.Sai Kumar MD

Vice Principal, SBMCH

Dr. Gunasekeran MS

Dean, SBMCH

	Intr	oduction to Clinical Research
S. No	Regn. No.	Name
1	. U17MB116	MALAVIKA G
2	U17MB117	MANOJ PRABHU V S
3	U17MB118	MANOJKUMAR J
- 4 - 5	U17M8119	MEENAKSHI B
6	U17MB120	MINIE HULDAH R
7	U17MB121	MOHAMED ARIF M
8	U17M8122	MOHAMEDROHETH R
9	U17MB123	MOHAMMAD TALHA SHADAN
10	U17MB124 U17MB125	MOHAMMED ABUBACKER SIDDIQUE
11	U17MB125	MOHAMMED FAISAL U MOHITH M P
12	U17MB127	MUDRAGADA PRANEETH
13	U17MB128	MUSKAN BANSAL
14	U17MB129	NANDHITHA NAIDU V
15	U17MB130	NATTISHA JENIFER B
16	U17MB131	NAVEENBALAJI G V
17	U17MB132	NAVIN A
18	U17MB133	NEELESH V
19	U17MB134	JUWAIN SHEHZAD NEHIL
20	U17MB135	NIGHIL AADHITHYA M
21	U17MB136	NISHANTH S R
22	U17M8137	NITHISH S
23	U17MB138	NIVEDHA V
24	U17MB139	NIVETHITHA N
25	U17MB140	PADMANABAN P
26	U17M8141	PAMURU YASHWITHA
27 28	U17MB142	PARKAVI G
28	U17MB143 U17MB144	PAUL REMIUS A
30	U17M8145	PAVITHRA P PAVITHRA RESHMA S
31	U17MB146	PAVITINA KESHIMA S
32	U17MB147	PEER MOHAMMED K
33	U17MB148	PONBARATHY V M
34	U17M8149	POOJA P
35	U17MB150	PRADAKSHINE S
36	U17MB151	PRADEEP G
37	U17M8152	PRADEEP M
38	U17M8153	PRADEEP KUMAR S
39	U17MB154	PRADHA RANJAN
40	U17MB155	PRAJIT N
41	U17MB156	PRANAV R P
42	U17MB157	PRAVEEN S
43	U17MB158	PRAVEENKUMAR S
44	U17MB159	PREETHI N
46	U17MB160	PREMALATHA R
47	U17M8161	PRITHA R J
48	U17MB162 U17MB163	PRIYADHARSHINI S
49	U17MB164	PRIYANKA KUMARI B PRIYANKA T
50	U17M8165	PRIYANKHA R
51	U17MB166	PUSHPA PREETHI A
52	U17MB167	RAGHUL PRASATH R
53	U17M8168	RAHUL P NAIR
54	U17MB169	RAIHANA
55	U17MB170	RAKSAI VARTH S
56	U17MB171	RAMALINGAM MADHUMITHA



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CORSE FEEDBACK FORM

Date: 9/7/18

Course Title: Introduction to clinical Research

Name: Pavidhra.s RegNo: U[7MB146 Department: Medicine

S.NO	Particulars Particulars	1	2	3	4	5
	(1. Very Unsatisfied 2. Unsatisfied 3. Neutral 4. Satisfied	15. Ve	ry sat	isfie	1)	<u>-</u>
	Objectives of the course clear to you	T	T		Ť	4
2.	The course contents met with your expectations					
3.	The lecture sequence was well planned	1		1		
4.	The lecturers were clear and easy to understand	1		1	-	
5.	The teaching aids were effective	1	1	1		
6.	The instructors encourage interaction and were helpful	1	1	1		
7.	The level of the course	1	†	1	-	 -
	(1. Very poor 2. Poor 3. Average 4. Good 5. E	xcelle	nt)	1		
8.		1	2	3	سه.	5

Please give suggestion for the improvement of the course:

Weakness of the course:

Strength of the course:

Pavithra. S Signature

Thank you

CORSE FEEDBACK FORM

Date: 10/7/18

Course Title: Introduction to elineal Reseach

Name: Malavika. Gr RegNo: UJAMB116 Department: Medicine

S.NO	Particulars Particulars	1	2	3	4	5
	(1. Very Unsatisfied 2. Unsatisfied 3. Neutral 4. Satisfied	15. Ve	ry sat	isfie	i)	
1.	Objectives of the course clear to you				~	
2.	The course contents met with your expectations		Ī	T		
3.	The lecture sequence was well planned	T		-		
4.	The lecturers were clear and easy to understand				~	<u>س</u>
5.	The teaching aids were effective			1	,,,,	
6.	The instructors encourage interaction and were helpful		1		-	
7.	The level of the course					-
	(1. Very poor 2. Poor 3. Average 4. Good 5. E	xcelle	nt)			
8.	Overall rating of the course:	ı	2	3	A	5

Please give suggestion for the improvement of the course:

Weakness of the course:

Strength of the course:

malavika 4 Signature

Thank you