

12/29/2021

Chennai

From

The Course Coordinator  
Principles and Practice of Clinical Research  
Department of ENT  
Sree Balaji Medical College  
Bharath Institute of Higher Education and Research,  
Chennai

To

The Dean  
Sree Balaji Medical College  
Bharath institute of Higher Education Research,  
Chennai

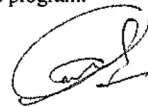
**Sub: -Permission to conduct value- added course: Principles and Practice of Clinical Research**

Respected sir,

With reference to subject mentioned above, the ENT proposes to conduct a value- added course titled: Principles and Practice of Clinical Research

We kindly solicit your kind permission to commence the program.

Warm Regards,



Course Coordinator

**SREE BALAJI MEDICAL COLLEGE & HOSPITAL**

CHROMPET CHENNAI -600044

Date: 12/31/2021

**R. No 340/ SBMCH/2022**

**CIRCULAR**

**Notification for Value added courses offered by the Department of ENT**

The Department of ENT of Sree Balaji Medical College is scheduled to offer a Value added Course on Principles and Practice of Clinical Research from 1/28/2022 for a period of 3 weeks. Interested students can approach the Head of ENT department and Course Coordinator, for registration and for further details on or before 1/21/2022.

**Eligibility-MBBS STUDENTS**

Course Coordinator



HOD

Copy to:

Dean office

Vice Principal

Medical Superintendent

AO College

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## PRINCIPLES AND PRACTICE OF 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	Hours allotted
GENERAL INTRODUCTION	Assistant Professor of Medicine	2 hours
EPIDEMIOLOGY & EVIDENCE BASED MEDICINE	Associate Professor of Medicine	2 hours

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

CLINICAL TRIALS		
Written test	Associate Professor of Medicine	2 hours



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



**CERTIFICATE**

This is to certify that Mr./Ms. has completed the value added course on Principles and Practice of Clinical Research conducted by ENT at Sree Balaji Medical College & Hospital, Chennai held during 1/28/2022.

**Dr.P.Sai Kumar MD**

Vice Principal, SBMCH

**Dr.Gunasekeran MS**

Dean, SBMCH

**Principles and Practice of Clinical Research**

S. No	Regn. No.	Name
1	U15MB229	THRILOK RAM B
2	U15MB230	TRUP MOHAMED FASIH MAAZ
3	U15MB231	UDAYA S
4	U15MB232	UTHAYASURYA K
5	U15MB233	VAIBHVI D
6	U15MB234	VAISHNAVI M
7	U15MB235	VANI KRISHNA
8	U15MB236	VARUN V
9	U15MB237	VASANTH S
10	U15MB238	VASANTHAKUMAR V S
11	U15MB239	VEENA KRISHNA
12	U15MB240	VENKATA MANISH REDDY MUNDLA
13	U15MB241	VIDHYAPRIYADARSHINI S
14	U15MB242	VIGNESH P
15	U15MB243	VIGNESH R
16	U15MB244	VIKAASH K S
17	U15MB245	VINITH M V
18	U15MB246	VINOTH G
19	U15MB247	YASHOPRIYADARSHINI V R
20	U15MB248	YAZHINI T
21	U15MB249	YUVARAJ L name changed as YUVARAJ LAKSHMIPATHY
22	U15MB250	YUVASHREE M
23	U15MB186	SHIRAVANKUMAR S P
24	U15MB187	SHONA NELSON
25	U15MB188	SHRIVIRUTHAA T
26	U15MB189	SHRUTHI SRI R G
27	U15MB190	SHRUTI U
28	U15MB191	SHUBAVEE R
29	U15MB192	SHYJU RAGLAND S R
30	U15MB193	SIDDARTH VINCENT RAJ S

COURSE FEEDBACK FORM

Date: 28/02/2022

Course Title: Principles and practice of Clinical Research

Name: Shanti. U

RegNo: U15MB190

Department: ENT

S.NO	Particulars	1	2	3	4	5
(1. Very Unsatisfied 2. Unsatisfied 3. Neutral 4. Satisfied 5. Very satisfied)						
1.	Objectives of the course clear to you					/
2.	The course contents met with your expectations					/
3.	The lecture sequence was well planned					/
4.	The lecturers were clear and easy to understand					/
5.	The teaching aids were effective					/
6.	The instructors encourage interaction and were helpful					/
7.	The level of the course					/
(1. Very poor 2. Poor 3. Average 4. Good 5. Excellent)						
8.	Overall rating of the course:	1	2	3	4	5

Please give suggestion for the improvement of the course:

Weakness of the course:

Strength of the course:

*Shanti U*  
Signature

\*\*\*Thank you\*\*\*



COURSE FEEDBACK FORM

Course Title: Principles and practice of Clinical Research Date: 28/02/22

Name: Yuvashree . M  
RegNo: U15MB250  
Department: ENT

S.NO	Particulars	1	2	3	4	5
(1. Very Unsatisfied 2. Unsatisfied 3. Neutral 4. Satisfied 5. Very satisfied)						
1.	Objectives of the course clear to you					/
2.	The course contents met with your expectations					/
3.	The lecture sequence was well planned					/
4.	The lecturers were clear and easy to understand					/
5.	The teaching aids were effective					/
6.	The instructors encourage interaction and were helpful					/
7.	The level of the course					/
(1. Very poor 2. Poor 3. Average 4. Good 5. Excellent)						
8.	Overall rating of the course:	1	2	3	4	5

Please give suggestion for the improvement of the course:

Weakness of the course:

Strength of the course:

Yuvashree . M  
Signature

\*\*\*Thank you\*\*\*

