

Introduction to the Principles and Practice of Clinical Research - Overview

National Institutes of Health (NIH), United States of America has selected **JSS University, Mysore** as a remote site to offer a certificate course in **‘Introduction to the Principles and Practice of Clinical Research (IPPCR)’** for the academic year 2011-12. The course will be conducted at JSS Colleges of Pharmacy, Mysore and Ooty, constituent colleges of JSS University.

The course on ‘Introduction to the Principles and Practice of Clinical Research’ was designed and offered to meet the needs of healthcare professionals and scientific researchers with an interest in the clinical research aspects of drug development.

The course consists of **FIVE modules** with twice weekly lecture series covering the fundamentals of clinical research including basic principles and epidemiological methods involved in clinical research. The course provides an overview to the ethics and legal issues involved in clinical research, and also the role of institutional review board, monitoring patient-oriented research and steps involved in performing, developing and funding research studies.

The course is taught by faculty members from the National Institutes of Health (NIH) and guest faculty from the Food and Drug Administration (FDA), the pharmaceutical industry and several academic and research institutions from across the United States.

Course Benefit:

The candidates can register for the course and obtain the certificate simultaneously without affecting the current job/ course. All the eligible participants will be issued with a certificate in recognition of successful completion of the course, including a final exam.

Contact Person:

For further questions or additional information regarding the ‘Introduction to the Principles and Practice of Clinical Research’ Course, please contact:

Dr. M. Ramesh

Event Liaison, IPPCR Course

Professor, JSS University

Department of Pharmacy Practice

JSS College of Pharmacy, SS Nagara, Mysore-15

Mobile: (0) 9901218640; E-mail: madhanramesh@hotmail.com

Please find below:

Course notification

Application form

Current course schedule

JSS University
JSS College of Pharmacy
Sri Shivarathreeshwara Nagara, Mysore-15

Date: October 3, 2011

Notification

National Institutes of Health (NIH), United States of America has selected JSS University, Mysore as a remote site to offer a certificate course in '**Introduction to the Principles and Practice of Clinical Research (IPPCR)**' for the academic year 2011-12. The course will be conducted at JSS Colleges of Pharmacy, Mysore and Ooty, constituent colleges of JSS University.

The *salient features* of the course are:

1. The course contains 36 lecture programmes, scheduled to be held between October 24, 2011 and March 26, 2012.
2. The course will be offered via videoconferencing and meet on every Monday and Tuesday evening from 5.30 pm to 6.30 pm.
3. All registered participants will be provided with required course materials.
4. A certificate will be awarded upon successful completion of the course, including a final exam.

Course Objectives:

- To become familiar with the basic epidemiological methods involved in clinical research
- To be able to discuss the ethical principles, legal issues and regulations involved in clinical research
- To become familiar with the principles and issues involved in monitoring patient-oriented research
- To be able to discuss the infrastructure requirements, and developing and funding of research studies

Course Benefit:

The candidates can register for the course and obtain the certificate simultaneously without affecting the current job/ course. The participants who successfully complete the course will be issued with a certificate in recognition of successful completion of the course, including a final exam.

Eligibility for the course:

1. B. Pharm/ PharmD/ BDS/ MBBS/ BAMS graduates
2. Postgraduate students of Pharmacy/ Dental/ Medical and Ayurveda
3. Pharm D (Post Bacculaureate) students

Course fee:

Rs. 5000/- for the entire course

Venue:

Seminar Hall, JSS College of Pharmacy, Mysore

Interested candidates are hereby informed to contact:

Dr. M. Ramesh

Event Liaison, IPPCR Course

Professor, JSS University

Department of Pharmacy Practice

JSS College of Pharmacy, SS Nagara, Mysore-15

Mobile: (0) 9901218640; E-mail: madhanramesh@hotmail.com

Dr. M. Ramesh

Event Liaison, IPPCR Course

Dr. H. G. Shivakumar

Principal

JSS University
JSS Medical Institutions Campus
Sri Shivarathreeshwara Nagara, Mysore-15

Affix your
passport size
photo here

**Registration Form for Introduction to the Principles and Practice of
Clinical Research (IPPCR) Course**

Centre: JSS College of Pharmacy, Sri Shivarathreeshwara Nagara, Mysore – 15

Name of the Candidate:		
Date of Birth:		Age:
Sex:		
Qualification (Degree):		
Name and address of Organisation:		
Mailing Address (Permanent Address):		
Contact Number:		
E-mail:		

I hereby declare that all those information provided in this application form is true, and understand that I will be disqualified from the course if the information provided in this form is found to be incorrect.

I hereby give my consent to take part in this course and abide by the course regulations. I am taking part in this course on my own wish.

Signature:

Date:

For Office Use Only	
Fee Remitted:	Yes / No
Remarks:	Accepted / Not accepted

Event Liaison – IPPCR Course

Principal

JSS University, Mysore

‘Introduction to the Principles and Practice of Clinical Research (IPPCR)’ Course

COURSE SCHEDULE FOR THE ACADEMIC YEAR 2011-2012

[October 24, 2011 – March 26, 2012]

All sessions will meet on Monday and Tuesday evenings from 5:30 p.m. to 6:30 p.m. in the Seminar Hall, JSS College of Pharmacy, Sri Shivarathreshwara Nagara, Mysore - 15

Introduction	
Monday, 24 th October 2011	Welcome (30 minutes) John I. Gallin, M.D. Director, NIH Clinical Center
	History of Clinical Research: A Merging of Diverse Cultures (30 minutes) John I. Gallin, M.D. Director NIH Clinical Center
Module I: Statistical Methods	
Tuesday, 25 th October 2011 Session 1	Unit 1: Design of Epidemiologic Studies (1.5 hours) Laura Lee Johnson, Ph.D. Statistician, Office of Clinical and Regulatory Affairs, NCCAM
Monday, 31 st October 2011 Session 2	Unit 2: Issues in Randomization (1.5 hours) Laura Lee Johnson, Ph.D. Statistician, Office of Clinical and Regulatory Affairs, NCCAM
Tuesday, 1 st November 2011 Session 3	Unit 3: Measures (1 hour) David Lukenbaugh, Ph.D. Biostatistician Experimental Therapeutics and Pathophysiology Branch, NIMH
Monday, 7 th November 2011 Session 4	Unit 4: Participant Selection (1 hour) Catherine Stoney, Ph.D. Program Director, Prevention and Population Sciences Program, NHLBI
Tuesday, 8 th November 2011 Session 5	Unit 5: Overview of Hypothesis Testing (1.5 hours) Laura Lee Johnson, Ph.D. Statistician, Office of Clinical and Regulatory Affairs, NCCAM
Monday, 14 th November 2011 Session 6	Breakout Session – (1 hour) Title – TBD, Laura Lee Johnson, Ph.D. Statistician, Office of Clinical and Regulatory Affairs, NCCAM
Tuesday, 15 th November 2011 Session 7	Unit 6: Secondary Data/Meta Analysis (1.5 hours) Charles Natanson, M.D. Senior Investigator and Head Anesthesia Section Critical Care Medicine Department, CC
Monday, 21 st November 2011 Session 8	Unit 7: Sample Size and Power (1.5 hours)
	Laura Lee Johnson, Ph.D. Statistician, Office of Clinical and Regulatory Affairs, NCCAM
Tuesday, 22 nd November 2011 Session 9	Breakout Session – (1 hour) Title – TBD Laura Lee Johnson, Ph.D. Statistician, Office of Clinical and Regulatory Affairs, NCCAM

Monday, 28 th November 2011 Session 10	Unit 8: Conceptual Approach to Survival Analysis (1.5 hours) Laura Lee Johnson, Ph.D., Statistician, Office of Clinical and Regulatory Affairs, NCCAM
Tuesday, 29 th November 2011 Session 11	Unit 9: Study Development (1.5 hours) Laura Lee Johnson, Ph.D. Statistician, Office of Clinical and Regulatory Affairs, NCCAM
Monday, 5 th December 2011 Session 12	Breakout Session – (1 hour) Title – TBD, Laura Lee Johnson, Ph.D. Statistician, Office of Clinical and Regulatory Affairs, NCCAM
Tuesday, 6 th December 2011 Session 13	Unit 10: Designing and Testing Questionnaires (1 hour) Kushang V. Patel, Ph.D, MPH, Laboratory of Epidemiology, Demography and Biometry, NIA
Monday, 12 th December 2011	RECESS
Tuesday, 13 th December 2011	RECESS
Monday, 19 th December 2011 Session 14	Unit 11: Efficient Clinical Trials (1 hour) John Powers, III, M.D. Senior Medical Scientist, NCI-Frederick
Module II: Ethical Issues and Regulation of Human Subjects Research	
Tuesday, 20 th December 2011 Session 15	Unit 1: Ethical Principles in Clinical Research (45 minutes) Christine Grady, R.N., Ph.D. Head, Section on Human Subjects Research, Acting Chief, Bioethics Department, CC
	Unit 2: Research with Vulnerable Participants (45 minutes) David Wendler, Ph.D. Head, Unit on Vulnerable Populations, Section on Human Subjects Research, Bioethics Department, CC
Monday, 26 th December 2011 Session 16	Unit 3: Legal Issues in Clinical Research (1 hour) Carrie Pottker-Fishel, J.D., Attorney Advisor, Office of General Counsel, NIH
Tuesday, 27 th December 2011 Session 17	Unit 4: Concepts in the Management of Projects (1 hour) Christopher Breder, M.D., Ph.D., Medical Officer, Center for Drug Evaluation and Research, FDA
Monday, 2 nd January 2012	Unit 5: Evaluation of a Protocol Budget (1.5 hours)
Session 18	TBD
Tuesday, 3 rd January 2012 Session 19	Breakout Session: Mock IRB (2 hours), Jerry Menikoff, M.D., J.D. Director, Office for Human Research Protections, Office of Public Health and Science, DHHS
Monday, 9 th January 2012	RECESS
Tuesday, 10 th January 2012	RECESS
Monday, 16 th January 2012	RECESS
Tuesday, 17 th January 2012	RECESS
Monday, 23 rd January 2012	RECESS

Tuesday, 24 th January 2012 Session 20	Unit 6: FDA Product Regulation (1.25 hours) Bette Goldman, R.N., M.P.H., Senior Advisor on Clinical Issues to the Associate Director for Review Management, Center for Biologics Evaluation Research, FDA
Monday, 30 th January 2012 Session 21	Unit 7: The Clinical Researcher and the Media (45 minutes) John Burklow, M.S., Associate Director for Communications, Office of Communications and Public Liaison, NIH
	Unit 8: Product Development: Moving from the Bench to the Clinic (45 minutes), Richard Schwartz, Ph.D. Chief, Vaccine Production Program Lab, Vaccine Research Center, NIAID
Tuesday, 31 st January 2012 Session 22	Unit 9: Clinical Research from the Patient's Perspective (1 hour) Jerry Sachs, Manager Guest Services (Retired) Smithsonian Museum of Natural History
Module III: Monitoring Patient-Oriented Research and Regulatory Issues	
Monday, 6 th February 2012 Session 23	Unit 1: Data and Safety Monitoring Boards (1 hour) Dennis O. Dixon, Ph.D., Retired NIAID Mathematical Statistician
Tuesday, 7 th February 2012 Session 24	Unit 2: Data Management in Clinical Trials (1 hour) Diane St. Germain, R.N., M.S., C.R.N.P., Nurse Consultant, Division of Cancer Prevention, NCI
Monday, 13 th February 2012 Session 25	Unit 3: Quality Control in Clinical Trials (1 hour) Kushang V. Patel, Ph.D., MPH, Laboratory of Epidemiology, Demography and Biometry, NIA
Tuesday, 14 th February 2012 Session 26	Unit 4: Scientific Conduct (1 hour) James L. Gulley, M.D., Ph.D., F.A.C.P. Director, Clinical Trials Group, Center for Cancer Research, NCI
Monday, 20 th February 2012 Session 27	Unit 5: Quality of Life (1 hour) John Ware, Ph.D., CEO and Chief Science Officer, QualityMetric, Inc.
Tuesday, 21 st February 2012 Session 28	Unit 6: NIH Peer Review Process (1 hour) Olivia Bartlett, Ph.D. Chief, Research Programs Review, NCI
Module IV, Preparing and Funding a Clinical Research Study	
Monday, 27 th February 2012 Session 29	Unit 1: Design of Case Report Forms (1 hour) Diane St. Germain, R.N., M.S., C.R.N.P., Nurse Consultant, Division of Cancer Prevention, NCI
Tuesday, 28 th February 2012 Session 30	Unit 2: Information Resources for Clinical Research (1 hour) Josh Duberman, M.L.I.S., Informationist /Research Librarian
Monday, 5 th March 2012 Session 31	Unit 4: ProtoType and Protocol Mechanics (1 hour) Philip Lightfoot, B.S., B.A., Systems Analysis, Department of Clinical Research Informatics, CC
Tuesday, 6 th March 2012 Session 32	Unit 5: Inclusion of Women and Minorities in Clinical Trials (1 hour) Miriam Kelty, Ph.D., Special Volunteer, Former Associate Director, Extramural Activities, NIA
Monday, 12 th March 2012 Session 33	Unit 6: Technology Transfer (1.5 hours) Bruce Goldstein, J.D. Unit Coordinator, Technology Transfer Branch, NCI

	Module V: Special Topics
Tuesday, 13 th March 2012 Session 34	Unit 1: Special Lecture: Human Genome Project and Clinical Research (1 hour) Christopher Austin, M.D.
Monday, 19 th March 2012 Session 35	Unit 2: Evaluation of Alternative and Complementary Therapies (1 hour) Marc Blackman, M.D., Associate Chief of Staff for Research and Development, Veteran's Administration Medical Center, Washington, DC
Tuesday, 20 th March 2012 Session 37	Unit 3: Health Disparities Research (1 hour) Kyu Rhee, M.D., M.P.P., FAAP, FACP Chief Public Health Officer, Health Resources and Services Administration, DHHS Irene Dankwa-Mullan, M.D., M.P. H. Acting Director, Office of Innovation and Program Coordination, NCHMC
Monday, 26 th March 2012 Session 38	Unit 4: Community-Based Participatory Research (1 hour) Francisco Sy, M.D., Dr PH, Director, Division of Extramural Activities and Science Programs, NCHMD

**Dr. M. Ramesh, Event Liaison, IPPCR Course & Professor, JSS University, JSS College of Pharmacy,
Mysore -15**

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