

Registration of participants for the Workshop on 'The New Regulations on Drug Trials in India', August 6, 2016

The workshop on 'The New Regulations on Drug Trials in India' is scheduled to start at 3.00 pm on August 6, 2016. In view of the limited number of registrations, the venue for the workshop will now be the AMCHSS Seminar Hall, III Floor, AMCHSS Building, SCTIMST.

We request all registered participants to complete the registration process by verifying their names and the spelling for their names between 2.30-3.00 pm in the lobby of the III Floor, AMCHSS Building.

We look forward to a productive session on August 6, 2016

Organising Team
SCTIMST

August 3, 2016



Institute Ethics Committee
Sree Chitra Tirunal Institute for Medical Sciences
& Technology, Trivandrum

Workshop on

'The New Regulations on Drug Trials in India'



Date: Saturday, August 6, 2016

Time: 3 PM to 5 PM

Venue: AMCHSS Auditorium, SCTIMST,
Thiruvananthapuram

Speaker:

Dr.Arun Bhatt, Consultant, Clinical Research
and Development.

He has over three decades of experience in the
Indian Pharmaceutical Industry, drug
development and regulatory affairs. He has
worked as President, Clininvent Research
Private Limited, a Clinical Research
Organisation, CEO of CME Private Limited and
Medical Director of Novartis India Limited. He
is the past President of the Indian Society for
Clinical Research (ISCR) and is the joint Editor
in Chief of Perspectives in Clinical Research, the
journal of ISCR.

Dr.Bhatt was nominated for the Honorary
Fellowship of the Institute of Clinical Research,
UK in 2009. He is a qualified assessor for the
National Accreditation Board for Hospitals and
Health Services (NABH) for clinical trials.

The New Regulations

The Central Drugs Standard Control
Organisation (CDSCO), Directorate of Health
Services, Ministry of Health and Family Welfare,
Govt of India has passed new regulations for the
conduct of drug trials in India and for review of
these trials by Ethics Committees. Since 2013,
the drug regulatory regime has undergone
changes to bring it in tune with International
regulatory frameworks.

Topics to be covered

Requirement for registration of Institutional
Ethics Committee with CDSCO

Compensation to participants in clinical drug
trials

Number of drug trials that a researcher can be a
part of simultaneously

Informed consent in clinical drug trials

Difference between academic trials and
regulatory trials

Institutional Ethics Committee Sree Chitra Tirunal Institute for Medical Sciences & Technology, Trivandrum

The Institutional Ethics Committee, SCTIMST
has been undertaking review of research
proposals for more than two decades. It has
undertaken training of researchers since 2004.

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<p style="text-align: center;">APPLICATION FORM</p> <p>Name:</p> <p>Qualifications:</p> <p>Affiliations/Designation:</p> <p>Method of paying the fess:</p> <p>Date:</p> <p>Signature:</p> <p>Note: Fees once paid cannot be reimbursed for those whose registration is accepted. Registrations will be confirmed by email by August 1, 2016.</p>	<p>These new regulations also have many local justifications that are discussed in the Ranjit Roy Chaudhury Expert Committee Report, July 2013. It is important to apprise researchers in the region of the new regulations and its implications for research by individuals and their institutions.</p> <p>Who can register: Medical professionals, health researchers, policy makers, health programme coordinators and other professionals who have at least a Masters in social sciences or Bachelors in any medical/health discipline</p> <p>Registration fees: Rs.300/- payable as demand draft payable at Thiruvananthapuram in the name of 'The Director', SCTIMST</p> <p>Number of seats: 200 seats are available on a first come first serve basis (your application will be considered only if the DD for Rs.300 is attached).</p>	<p>Deadline for registering: July 27, 2016 (4 pm). Your applications should reach the office of the IEC, SCTIMST, 5th Floor (with the accompanying demand draft for Rs.300)/-</p> <p>A few on the spot registrations on August 6, 2016 will be entertained. The fees for spot registration will be Rs.400/- payable in cash at the cash counters, Medical Block, SCTIMST.</p> <p>If you are interested in participating in this workshop, please register for participation by sending an email to iecsctimsttraining@gmail.com on or before 4 PM, July 27, 2016. Please use the attached application form at the back of the 1st page of the brochure and your demand draft to: IEC Office, AMCHSS Building, SCTIMST, Thiruvananthapuram 695011 to reach us before July 27, 2016. (4 pm)</p> <p>You will be informed if your registration has been accepted. For those whose registrations are not considered (because the available number of registrations are already filled or because the candidate does not fulfil the eligibility criteria, will be informed by email and they can collect their DDs at the specified time mentioned in the emails to them.</p>
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