ETHICS CONFERENCE

A National Conference on Evolving Roles of Ethics Committees in India

(First Edition)

Date: 31st May and 1st June, 2013
Time: Day-1: 9:00 AM to 5:00 PM
Day-2: 9:00 AM to 3:00 PM

VENUE: "Jacaranda", Habitat World, at IHC, Lodhi Road, New Delhi-110003

Organised by: Apollo Hospitals Educational and Research Foundation

Championing Ethics for India...

Conference Format: A 1 & ½ Days program with 7 plenary sessions, 2 Panel Discussions, 1 Workshop.

Who Should Attend:

- Ethics Committee members, Institutional Heads/representatives, Investigators and coordinators, members from National Regulatory bodies.
- Directors, Vice Presidents, Senior Managers/Associates from Sponsor & CRO Companies.

Conference Objectives

- To provide an overview of the *modus operandi* of the Ethics Committee.
- To provide practical training about the review and oversight of clinical trials.
- To discuss the development of Guidelines and laws governing Ethics Committee.

Benefits to Participants:

- *A sensitization of key stakeholders towards the Guidelines and laws.*
- *An insight into the review and oversight mechanism for compliance with the statutory requirements.*
- *The speakers will provide tools which will be helpful to standardize the processes of EC.*

Introduction: With the evolving needs of Industry and the new Regulations, it is the need of the hour for the key stakeholders to prepare adequately for the road ahead. Such preparation shall ensure that the clinical research industry grows and matures steadily yet responsibly.

Program of Plenary sessions & Panel Discussions:

- ✓ Recent changes and current status of clinical research regulations
- ✓ Overview of provisions, status and outlook on registration of Ethics Committees
- ✓ Key gaps currently existing in the governance of clinical trials - Informed consent, Functioning of Independent and Institutional Ethics Committees, Compensation for Injuries and Financial transactions in clinical trials
- ✓ Accreditation of Ethics Committees and essential requirements (Inspection and audits, Standard Operating Procedures and Governance)
- ✓ ***Panel Discussion:*** Impact of new regulations on clinical research in short term and long term from stakeholders' perspective.
- ✓ Review of projects by Ethics Committee (Key elements of review and analysis, Risk-benefit ratio, Studies with Vulnerable subject, Placebo use etc.)
- ✓ Specific considerations for review of studies involving Special products/phase *(Stem cells, Tissues for Research, Medical Devices, Phase 1 Trials, Bio-equivalence Studies, Post marketing, registry & observational studies and Biologicals)*
- ✓ Training Needs and Systems for orientation, training, and development of Ethics Committee members.
- ✓ ***Panel Discussion:*** Opportunities and Challenges for Ethics Committees in governance of Clinical Trials in India.
- ✓ ***Workshop:*** **Step by Step Role Play of Ethics Committee:** From receipt of Research Application to organizing the meeting, Review of application, Grant of approval, Continuing Review, Drafting letters of approval/ rejection / query and drafting minutes of meeting, Review of SAEs and Determination of Compensation
- ✓ **Vision for the future of Clinical Research in India, by Prof. Ranjit Roychaudhury**

Key Speakers: *Prof. Ranjit Roychaudhury, Dr. Nandini Kumar, Dr. Roli Mathur, Dr. R. Ramakrishnan, Dr. Mubarak Naqvi, Dr. Shoibal Mukherjee, Dr. Raman Govindarajan, Dr. Chirag Trivedi, Dr. Arani Chatterjee, Dr. Milind Antani, and other experts from industry.*

Registration Fee:
- For Pharmaceutical companies/CRO: Rs. 2500.
- For Hospitals/Ethics committees: Rs. 1500 (Rs. 1000 for Early registration upto 10th May, 2013).

For more details, please contact: Mr. Gourav Kumar, Member Secretary, Ethics Committee, Apollo Hospitals, Hyderabad at +91 99896 71343; Ms. V. Shalini Reddy, AHERF, Hyderabad at +91 40-23431726;

Conference Email: ethicsconference@aherf.net ;

Event Supported By