

## CALL FOR APPLICATIONS

**5<sup>th</sup> Institute on ethical conduct in biomedical research, post  
trial access to medicines, regulation and Law**

**A THREE-DAY COURSE  
ON**

**ETHICAL AND LEGAL ISSUES IN  
'NEW FRONTIERS' IN BIO-MEDICAL RESEARCH**

**13th to 15th July, 2018  
HYDERABAD**

**ORGANISER:  
SAMA-RESOURCE GROUP FOR WOMEN AND HEALTH**



([www.samawomenshealth.in](http://www.samawomenshealth.in))

## **ABOUT SAMA**

Sama-Resource Group for Women and Health is a Delhi based organisation working on issues of women's rights and public health. Sama's core work revolves around ethics and governance of clinical trials, strengthening of the public health system, health particularly sexual and reproductive of marginalized communities, reproductive and medical technologies, and access to medicines. Sama engages with a range of groups, organisations, networks and people's health movement through policy monitoring and advocacy, capacity building, knowledge creation and dissemination.

Sama has been a part of the Committee developing the revised guidelines for Biomedical Research on Human Participants by Indian Council for Medical Research (ICMR), contribute comments to the Council for International Organizations of Medical Sciences (CIOMS) guidelines for World Health Organisation (WHO) and for the revised Helsinki declaration by the World Medical Association (WMA).

Sama has been a part of the National Bioethics Conference (NBCs), an initiative of the Indian Journal of Medical Ethics (IJME) to establish a broad, independent, and participatory national bioethics platform. Sama co-organised the Third National Bioethics Conference held in 2010 in Delhi. Sama is also a co-organiser of the 14th World Congress of Bioethics, which is scheduled to be held in December 2018 (See Congress website <<http://ijme.in/nbc-20140321/index.php/14th-wcb-india/index/pages/view/home-page>>) in India. More information about Sama and its work can be accessed on Sama's website <[www.samawomenshealth.in](http://www.samawomenshealth.in)>.

For the past five years Sama has been conducting capacity building courses through its Institute on ethical conduct in clinical research, post trial access to medicines regulation and Law on ethics in clinical research – informed consent, compensation, access to medicines, patents and pricing etc. The previous Institutes were held in Bhopal, Delhi and Mumbai. Sama has trained about 150 participants including health researchers, health professionals, ethics committee members, students, social scientists, and activists working on gender, public health and other regulatory issues. During these years, Sama's capacity building courses have also been an opportunity to initiate public discourse on emerging issues in medical research.

Taking the initiative forward, this year, Sama is organizing a three-day course on “ETHICAL AND LEGAL ISSUES IN ‘NEW FRONTIERS’ OF BIO-MEDICAL RESEARCH” from 13th to 15th July, 2018.

## ***COURSE CONTENT***

The three-day course will broadly cover the following topics:

**Introduction to Clinical Trials:** The course will provide an introduction to clinical trials, structure of organization of clinical trials and the current scenario.

**Biological drugs:** These are the new-frontier of disease control lies in finding remedies that can effectively cure and control cancers and several degenerative diseases. The main issues with regulations are regulatory issues and intellectual property issues. The regulatory procedures need to be streamlined to ensure that entry of biosimilars ensuring the quality and safety.

**Revised Ethical Guidelines in Bio-Medical Research:** The course will focus on the significance of ethical conduct in health research. An orientation will be provided on the national and international standards and regulations in conducting research involving human participants.

**New amendments to clinical trial regulatory laws:** The course will address the new rules, amendments brought to law governing clinical trials in India. It will focus on issues relating to post trial access to medicines and clinical trial compensation.

**Controlled Human Infection Model (CHIM) Studies:** CHIM is a type of medical research which the Department of Biotechnology (DBT) and Indian Council for Medical Research (ICMR) are planning to introduce in India. CHIM studies allow intentionally infecting a healthy volunteer to test the efficacy of a vaccine. The course will examine ethical and legal paradigm around CHIM studies in Indian context.

## ***PARTICIPANTS***

This interactive course will be of interest to ethics committee members, medical professionals, legal professionals, researchers, early career researchers, students, academics, civil society and health right activists working in the field of public health, women’s health, and access to medicines, patients’ perspectives and bioethics. However, the course is open for participation to anyone who may be interested.

## ***VENUE AND DATES***

Venue: Hyderabad

Date: 13, 14 and 15 July 2018

## ***ACCOMMODATION AND TRAVEL***

Lodging and food will be arranged by Sama for all the participants during the entire duration of the course.

Participants are requested to make their own travel arrangements once they receive confirmation regarding selection of their application from Sama. **There is no registration fee for this short course.** The course will be conducted mainly in English.

## ***SELECTION PROCESS***

Interested participants are requested to send in the completed application form by 30th June, 2018 to the email id <samacommunication01@gmail.com>, with the subject line-‘Application for Sama course’. Please submit your application at the earliest. Selection will be based, on the ability to demonstrate the future application of the course content and the interest, work experience and/or engagement related to the areas covered by this course.

Participants will be informed of their selection by email only. This is a residential course, so participants would be required to stay at the venue for the entire duration (3 days) of the course.

Institutes and organizations that may want to send their students/faculty may send a maximum of two participants.

**CORE FACULTY INCLUDE** Dr Amar Jesani, Adv Veena Johari, S. Srinivasan, Dr Anant Bhan, Dr. Santanu Tripathi, and Sarojini Nadimpally

*Any queries or clarification with regard to participation in this course may be directed to <samacommunication01@gmail.com>, or <sama.womenshealth@gmail.com>*