



National Institutes  
of Health

# International Workshop on Clinical Research Ethics

15<sup>th</sup> & 16<sup>th</sup> November 2019

**KIIT Deemed to be University,  
Bhubaneswar, Odisha**  
*in collaboration with*  
**Department of Bioethics,  
National Institutes of Health (NIH), USA**



## Venue

**Kalinga Institute of Medical Sciences,  
KIIT Deemed to be University, Bhubaneswar, Odisha**

*Patron in Chief*  
**Prof. A. Samanta,**  
Founder, KIIT & KISS

*Chairman Organizing Committee*

**Maj. Gen. (Prof.) Dr. P. K. Patnaik, VSM**  
Principal, KIMS & Director,  
School of Medicine

*Organizing Chairman*

**Prof. Santosh Rath**  
Dept. of Orthopedics, KIMS

*Organizing Joint Chairmen*

**Prof. R. C Das**  
HoD, Psychiatry, KIMS  
**Prof. S. K Rath**  
HoD, O & G, KIMS

*Organizing Secretaries*

**Dr. Alpana Mishra**  
Asst. Professor,  
Community Medicine, KIMS  
**Dr. Magna Manjarika**  
Assoc. Professor,  
Physiology, KIMS  
**Dr. Soumya Mishra**  
Asst. Professor,  
Physiology, KIMS

*Organizing members*

**Dr. Mona Pathak**  
Biostatistician, KIMS  
**Dr. Sibanarayan Rath**  
Research Associate, KIMS  
**Miss. Lipika Sahoo**  
Trainee (DEO), KIMS

*Advisors*

**Padma Shri Prof. Subrat Ku. Acharya**  
Pro Chancellor,  
KIIT Deemed to be University  
**Prof. Sasmita Samanta**  
Pro Vice Chancellor,  
KIIT Deemed to be University  
**Mr. R. N. Dash, IAS (Rtd)**  
Secretary KIIT & KISS  
**Prof. S. Nanda**  
Prof. Emeritus & Research Chair,  
KIIT  
**Padma Shri Prof. Y. K Chawala**  
Chairman Academics, KIMS  
**Admiral Prof. A. C. Anand, VSM**  
HoD, G & E, KIMS  
**Prof. Jnana R. Mohanty**  
Registrar,  
KIIT Deemed to be University  
**Dr. Bishnu P. Panigrahi**  
CEO, KIMS  
**Prof. S. C. Raina**  
Director, KIIT School of Law  
**Prof. Mrutyunja Suar**  
Director, KSBT  
**Dr. Sujata Acharya**  
Principal, KISS

## Agenda Setting Workshop for Clinical Research in India

At the moment India is developing capacity for research and product development in the biopharmaceuticals and there are several initiatives that provide investment in product development and build research infrastructure. One necessary component of such infrastructure is regulatory and ethical capacity, which is lacking in India. KIIT Deemed to be University, Bhubaneswar in collaboration with the Department of Bioethics at the US National Institutes of Health (NIH) will organize an agenda setting workshop to explore how such academic clinical research, ethics infrastructure can be developed in India. The Department of Bioethics National Institute of Health (NIH), USA will be represented by world renowned bioethics researchers: Christine Grady, David Wendler, Joseph Millum, Koneti Rao and Reidar Lie. In addition three leading Indian scholars in bioethics, formerly of ICMR, will be the participants.

On first day, topics related to knowledge gap in ethical issues on future research, related to children and other vulnerable groups who cannot give consent, will be discussed issues in the population. The second day will be devoted to discussion to establish and develop academic infrastructure for clinical research ethics in India. The US participants will provide insight based on their experience with development of academic research at NIH. Key policymakers from Government of India and National Institutes are expected to engage in the discussions. Your participation in these deliberations is crucial to guide the agenda and propose suitable actions for India. Your contributions will enable the expert group to identify a roadmap for the establishment and development of research ethics infrastructure in India, a necessary step for the development of globally competitive biopharmaceutical research in India.

This workshop will be a unique opportunity for those who are involved in clinical research and product development in India to learn about the latest developments in research ethics. It will also give young researchers who are considering a career in bioethics, a chance to learn about opportunities for research collaborations with renowned international experts.

# Programme Structure

## Day- 1 (November 15, 2019)

9:00	Welcome and opening address Representatives from KIMS, NIH and others
9:30	The ICMR guidelines: with special reference to research with children, standard of care and post-trial benefits. Experience with videotaping of the informed consent process by Dr. Vasantha Muthuswamy
<b>10:30</b>	<b>Break</b>
11:00	Informed consent, including empirical work by Dr. Christine Grady.
12:00	Research with children and other groups that cannot give consent by Dr. David Wendler
<b>13:00</b>	<b>Lunch</b>
14:00	Research in indigenous populations
<b>15:00</b>	<b>Break</b>
15:30	Standards of care and post-trial benefits by Prof. Joseph Millum
16:30	Concluding discussion End of day one

## Day -2 (November 16, 2019)

9:00	Roundtable: Challenges in Ethical review & Identification of gaps based on first day of discussion Dr. Vasantha Muthuswamy Dr. Nandini Kumar Dr. Koneti Rao Prof. Reidar Lie
<b>10:30</b>	<b>Break</b>
11:00	Current needs as identified by key stakeholders- CROs Representatives ICMR, DBT, BIRAC
<b>13:00</b>	<b>Lunch</b>
14:00	Roundtable to identify current challenges in clinical research ethics, capacity building for quality ethics review and moving towards institutional review board (IRB) in India. Moderated by Dr. Koneti Rao & Prof. Reidar Lie
16:30	Implementation proposal for capacity building for quality ethics review & research by representatives from each participating department
17.00	Summing up End of day two

# International Workshop on Clinical Research Ethics

**KIIT** is committed to high-quality research and provides outstanding facilities and a supportive environment for our academics and students. KIIT's research portfolio extends across many different areas including, biotechnology, medicine, rural management, physical activity and nutrition, education, and social and mental health including Yoga. It had its inception in 1992 by famous educationalist and social entrepreneur, Dr. Achyuta Samanta, popularly known as Hon'ble founder of KIIT & KISS.

## **Kalinga Institute of Medical Sciences (KIMS)**

KIMS offers a unique combination of experience and expertise. Located in an ultra-modern and eco-friendly campus, it has two wings – The Hospital and The Medical College. A high academic standard is maintained by an experienced and dedicated team of professors, clinicians and scientists, who are engaged in teaching research and developing technologies in health care. The courses are approved by Ministry of Health and Family Welfare, Govt. of India and Medical Council of India (MCI). The Medical College has 21 academic departments, providing the study, treatment and prevention of human diseases and maternity care.

## **KIIT-Technology Business Incubator (KIIT-TBI)**

KIIT-TBI creates opportunities through its incubator, accelerator and market access programs curated for startups, enterprises, knowledge sharing workshops, investor connects and sector based networking events.

## **KIIT School of Biotechnology (KSBT)**

KSBT foundation was undertaken with the mission of “Science for Society” to have integrated academic and research programmes with skilled human resources in the field of biotechnology and microbiology and provide all round nurturing environment for overall scientific growth of students

## **KIIT School of Law (KSOL)**

KSOL has established itself as a pivotal Institution of excellence, scholarship and rigour among the law institutions of the third generation. It offer specialized honours courses in Constitutional Law, Business Law, International Law, Crime and Criminology, Intellectual Property Law and Taxation Law.

## **Kalinga Institute of Social Sciences (KISS)**

KISS is a residential institute for tribal people based in Bhubaneswar, India. It provides accommodation, study, career development, and healthcare to 30,000 tribal students each year at its integrated residential campus located in Bhubaneswar. A unique social revolution with global recognition and cultural a cauldron.



**Prof. A. Samanta**  
Founder, KIIT & KISS

**Resource Persons**



**Dr. Christine Grady**  
Chief, Department of  
Bioethics, NIH Clinical Center



**Dr. Reidar K. Lie**  
Consultant, NIH,  
USA



**Dr. Joseph Millum**  
Ethics and Educational consultant,  
Fogarty International Center,  
Bethesda, USA)



**Dr. David Wendler**  
Bioethics consultant,  
NIH Clinical center



**Dr. K. Rao**  
Physician at NIAID conducting  
clinical research and  
Chair of NIAID  
Institutional Review Board



**Dr. Nandini K Kumar**  
Deputy Director  
General Senior Grade (Rtd.)  
at the ICMR



**Dr. V. Muthuswamy**  
Senior Deputy Director General  
(Retd. at ICMR)



**Padma Shri  
Prof. S. K. Acharya,**  
Pro Chancellor,  
KIIT Deemed to be University



**Prof. Hrusikesh Mohanty,**  
Vice Chancellor,  
KIIT Deemed to be University



**Prof. Sasmita Samanta**  
Pro Vice Chancellor,  
KIIT Deemed to be University



**Maj. Gen. (Prof.) Dr. P. K. Patnaik, VSM**  
Principal,  
KIMS & Director, School of Medicine



**Dr. Santosh Rath**  
Organizing  
Chairman

## Registrations

We have the pleasure and honor to invite nominations or participants to attend the workshop on November 15<sup>th</sup> and 16<sup>th</sup> 2019. Registration is limited to 200 participants. There is no delegation fee. However, delegates have to bear their own travel and accommodation expenses. **Last date of registration is 31<sup>st</sup> October 2019.**

## Details of Contact persons:

### Registration Form

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#### **Dr. Alpana Mishra**

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#### **Prof. Santosh Rath**

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***Organizing Chairman***  
Mobile No: +91-9583373285

## How to reach Bhubaneswar:

Biju Patnaik International Airport, Bhubaneswar connects the city with rest of the country by air. From the airport, taxi/bus services are available to reach KIIT Deemed to be University. Bhubaneswar Railway Station is the main railhead connecting the city with several Indian cities. From the station, you can take private cabs or taxis to reach venue. The distance of venue around 13 k.m. from Airport and 11 k.m. from the Railway station.

KIIT Guest House is a value for money accommodation in Bhubaneswar situated 1.5 km away from venue. Paid airport transfer service is also offered for the convenience of the guests. For booking contact: Mr Anil Panda, Ph No: +919437421150

# Registration Form

*Registration through E-mail at kiitnihethics@gmail.com*

Name:..... Age:..... Gender:.....

Designation:.....

Institute/ Organization:.....

Mailing address:.....

City:..... Pin Code:.....

Mobile No:.....

E-Mail ID:.....

## **Brief bio on Research & ethics Activities (100 words)**

**Reason for attending the workshop 2/3 lines**