Summary of the 2 day KIMS NIH Bioethics Workshop:

Day 1:

On November 15, 2019 at 9am KIMS-NIH Bioethics workshop commenced with a ritual lamp lighting by NIH faculty leader Dr.Christine Grady. The ceremony was followed by welcome comments from KIMS University Vice Chancellor, Principal of KIMS and keynote speech by Dr.Grady. All of them underscored the need for infrastructure in clinical research ethics as an integral part of capacity building in clinical research. It was expected that this workshop would facilitate efforts at KIMS to set up a structured training program in bioethics that would foster a career path for the future leaders in the field. Such a program would need support from funding and regulatory bodies (industry, ICMR, Drug Controller), and policy making bodies (NITI ayog) at the National and the State level. Many of these entities were represented at this two-day deliberative workshop. Evolution of ICMR clinical research guidelines: 1980 to 2017was the focus of Dr.V. Muthuswamy's presentation. Dr.Grady and Dr.Wendler from NIH discussed the challenges in ensuring appropriate consent in clinical research and nuances in proper Informed Consent Process with special emphasis on research with children & other vulnerable population groups that cannot give consent. Dr.Joseph Millum from NIH Fogarty International Center focused on prevailing standards of care and commitments to post trial benefits in resource poor settings.Dr. Vinod Paul from NITI Ayog gave an aspiration viewpoint related to the emerging clinical research potential in India. It aligned with the main goal of this workshop to establish national resource centers of research in bioethics, create a cadre of bioethics professional in India in order to build clinical research capacity in all academic medical centers.

Day 2:

The 2nd day of the workshop started with the topic of Research in Indigenous Populations by Dr. Ramadass Balamurugan from AIIMS, BHUBANESWAR. He discussed the challenges and dilemmas encountered by researchers while visiting study site in tribal villages and how to deal with real life problems of subject recruitment and research sample collection for the microbiome study. Dr. John Oomen from Christian Hospital, Bissam Cuttack, highlighted the real world challenges faced while delivering health care to indigenous communities and perspective from the other end of the microscope. He elaborated on many encounters with clueless novice medical researchers that are unable to generate a buy-in from the study subjects while embarking on doing research on tribal communities and vulnerable groups. He stressed on language and cross culture communication barriers and various types of bias. Dr. Chetan Desai who is the Senior Medical Director at IQVIA, explained the current

needs for clinical research ethics and capacity building of IRBs. Dr. Arani Chatterjee of Aurobindo Pharmaceuticals discussed about readability of informed consent and lack of various grades of readability scores for regional Indian languages. Dr. Sucheta Banerjee Kurundkar who is the Director Training, Clinical Development Services agency of DBT discussed about perceived need for ethics review and Indian Government's efforts for capacity building. Their agency trains people about ethics. They have various online courses planned in collaboration with IIT Madras. Dr. Dhananjay Sable, Assistant Drugs Controller (India),CDSCO gave an excellent presentation about new clinical trial rules involving new drugs. He also discussed rules governing Test license, Academic clinical trial, Clinical trial waiver, provisions for waiver in clinical trials involving orphan drug, audit of informed consent procedures. Dr. S. Rajesh, Director at NITI Aayog, discussed about regulatory policy framework, integration and convergence of research groups and stake holders, quality control of IRBs. Discussions of IEC should be documented as meeting minutes including deliberations related approvals and disapprovals. In the post lunch session, round table discussion was held which was moderated by Dr. Reidar Lie and Dr. V. Koneti Rao. Various questions were asked by participants like reimbursement to participants, SAE and death, audit and monitoring, involvement of 3rd party laboratory, vulnerability levels of participants, informed consent comprehension and translation, limits on number of Clinical Trials a PI may be involved in, broad consent involving research on biological tissues. The workshop ended with concluding remarks and vote of thanks by Prof. Santosh Rath.