

# Rajasthan University of Health Sciences, Jaipur



## Research Methodology-Ethical Aspects of Biomedical and Health Research

**Organized by : Rajasthan University of Health Sciences, Jaipur**  
**Dates : 8<sup>th</sup> - 9<sup>th</sup> April, 2017**

### Overview

A 2 day workshop on ethical aspects of biomedical and health research is envisaged to enhance the knowledge and skill sets of researchers, teaching faculty, clinicians ( mainly faculty of medical colleges/ institutions ) , through an extensive exposure on approaches for role and need of the ethical aspects in biomedical and health research, developing a research plan , research ethics-history & international guidelines, drugs and cosmetics act & good clinical practice guidelines, informed consent process, role and responsibilities of institutional ethics committees, ethical issues in genetics and stem cells research including public health, conflict of interest, issues in research etc. This workshop will facilitate the participants to realize their potential as clinical researchers on clinical/therapeutic/biomedical/public health/other health related areas and will be useful to improve their knowledge and its applicability in day to day practice/public health.

### Major Workshop Content:

- ⇒ Role and need of the ethics in biomedical and health research
- ⇒ Research ethics- history & international guidelines
- ⇒ ICMR ethical guidelines for biomedical and health research
- ⇒ Drugs and cosmetics act & good clinical practice guidelines
- ⇒ Informed consent process
- ⇒ Role and responsibilities of institutional ethics committees
- ⇒ Regulatory and non regulatory clinical trial issues
- ⇒ Ethical issues in genetics and stem cells research
- ⇒ Conflict of interest issues in research

### Expected outcome:

- ⇒ Knowledge of ethics in research
- ⇒ Developing research projects keeping in view the national priorities along with ethics
- ⇒ Starting research project with minimum funding on pilot scale with institutional ethical approval
- ⇒ How to take informed consent form the subject

### **Eligibility criteria:**

Researcher/ Clinician working in area of biomedical research / faculty in a medical college/institution.

### **Selection criteria:**

- ⇒ Participants will have to submit a **Concept Note** (150-200 words) on the topic of their interest and how would they utilize the knowledge of workshop along with registration form.
- ⇒ Scanned copy of registration on form on email id [vdruhs@gmail.com](mailto:vdruhs@gmail.com)
- ⇒ **Concept Note** will be reviewed by selection committee to select **candidates for the workshop**.
- ⇒ **Selection committee's decision will be final.**

**Number of seats: Limited Eighty (80) only.** (*On first come first serve basis and merit of concept proposal*)

### **Registration dates:**

**Open on: 01/03/2017**

**Close on: 25/03/2017**

**Workshop Coordinator: Dr. Sudhanshu Kacker**

### **For Registration and Details Contact:**

Dr. Sudhanshu Kacker, Prof. & Vice Dean (Acad. and Res.)

Ph. 9983723535

Dr. Sunil Gupta, Assistant Professor, RUHS

Ph. 9414338772

Dr. Reshu Gupta, Assistant Professor, RUHS

Ph. 9928298565

Dr. Setu Mathur, Assistant Professor, RUHS

Ph. 9799942484

# About Resource Faculty



**Dr. Roli Mathur**



**Dr. N. C. Jain**



**Dr. Nandini K Kumar**



**Dr. Nalin Mehta**



**Dr. V. M. Katoch**



**Dr. Bharti Malhotra**



**Dr. Hemant Malhotra**



**Dr. Kiran Katoch**

## About Resource Faculty

### **Dr. Roli Mathur:**

Dr. Roli Mathur presently working as Scientist-E at National Centre for Diseases Informatics & Research (NCRP), Bengaluru. She is an eminent scientist in the field of Biomedical and health research. She has given many lectures on ethical aspects of Biomedical and Health Research. She has done many foreign visits regarding 11<sup>th</sup> Global summit of National Ethics to Germany in 2016, Participation in the piloting training tool for implementation research ethics to Indonesia in 2015 and attended a meeting at Washington (USA) regarding the 2013 middleton international fellows association leadership committee in 2013.

### **Dr N. C. Jain:**

Dr. N.C. Jain presently working as Director, Scientist-G and Head, Human Resource (Planning and Development), Indian Council of Medical Research (ICMR), New Delhi. He is an eminent scientist in the field of Biomedical and Health Research. He has given many lectures on ethical aspects of Biomedical and Health Research. He is a life member of Society for Information Science, New Delhi also a life member of Indian Science Writers Association, New Delhi. He has awarded in 2012 as fallow, Society for Information Science (SIS), New Delhi. He has got the prestigious Dr. B.C. Deb Memorial Award for Popularization of Science in 1997 in Indian Science Congress Association, Kolkata. He has awarded Raizada Memorial Award in 1992 for Young Information Scientist for the Society for Information Science, New Delhi. He has participated in International Workshop on Webometrics, Informetrics, Scientometrics and Seventh Collenet Meeting in France in 2006. He is also participated in 9<sup>th</sup> International Confrence of Scientometrics Informetrics in China in 2003.

# About Resource Faculty

## Dr V M Katoch:

Dr. V. M Katoch did his MBBS-1974 (Shimla), M.D. 1978 (AIIMS, New Delhi); VA Medical Centre, Long Beach, CA, USA (1980-81) ; National Institute for Medical Research, London, UK (1984-85); other specialized trainings; Joined Indian Council of Medical Research (ICMR) for Talent Search Schemes (TSS) Fellows; posted at JALMA Agra in 1978, Director of this Institute in December 2001- Nov 2008 ; Served as Founder Secretary of Department of Health Research (DHR) & Director-General, ICMR ; Ministry of Health and Family Welfare, Govt of India, from 18th Nov 2008 to 28th February, 2015. Currently: NASI-ICMR Chair on Public Health Research at RUHS,Jaipur .

Dr. Katoch has developed and implemented over 25 extramural projects from DST, DBT, ICMR etc. He is developer of modern methods of rapid diagnosis of TB, leprosy, DNA chips; DNA fingerprinting methods etc.; contributed to expansion of mandate of JALMA from leprosy to all mycobacterial diseases.

As the founder Secretary of new department, played important role in developing and implementing five new schemes to accomplish nine new business – (i) establishment of multi-disciplinary research units (MRUs) in government medical colleges ( with focus on NCDs, RCH, gender issues etc; (ii) Model Rural Health Research units (MRHRUs three partners - medical college, state services and ICMR/ other apex institutes for taking the technology to people- (iii) Virology Research Laboratories in states and medical colleges (iv) Scheme for Human Resources for Health Research focus on medical colleges ; (v) Grant in Aid scheme for projects focused on intersectoral collaboration and coordination. ICMR, 10th function of DHR and an 104 year old ( established 1911) reputed autonomous organization, which saw a major drive towards modernization earlier, gave major thrust on innovation and translation ; establishment of Tribal Health Research forum with focus on tribal and marginalized communities; Vector Borne Diseases Forum etc. during these years. Dr Katoch has contributed over 280 research papers in Indian and foreign journals. He is recipient of various awards : Young Scientist Award of IAMM 1985; Shere-I-Kashmir Sheikh Abdulla Memorial Oration Award 1989; Dr.CGS Iyer Oration Award of ICMR 1990; Erwin Stindl Memorial Oration Award of German leprosy Relief Organization 1991; Dr. S.C. Agarwal Oration Award of IAMM 1994; Dr. Manu Patel Prize of IADV 1999; JALMA Trust Fund Oration Award 1999 of ICMR, IAMM Endowment Award 2003; Ranbaxy Science Foundation Award 2004; UC Chaturvedi Life Time Achievement Award 2009; Mellanby Oration 2009; Vishwanathan Oration 2009; Maj Gen. Sahib Singh Sokhey Oration 2009; Excellence in technology award of ISC 2011 ; PC Ray Award 2012 etc. ; Dr Katoch is fellow of national science academies of country : National Academy of Sciences (FNASc); Fellow of National Academy of Medical Sciences (FAMS); Fellow of Academy of Sciences, Bangalore (FASc); Fellow of Indian Academy of Science (FNA).

## About Resource Faculty

### **Dr Nandini K Kumar:**

Earlier as Program Officer for bioethics, pharmacology and traditional medicine research in the Indian Council of Medical Research (ICMR), New Delhi. She had experience in organizing several workshops on ethical issues involving biomedical research and traditional medicine research for ICMR, national and international Groups. She was closely involved in finalisation of ICMR's revised Ethical Guidelines of 2000, and its revision of 2006, finalization of National Guidelines on Stem Cell Research and Therapy (2007) and Stem Cell Research (2013) and Rules for evaluation of ASU (Ayurveda, Siddha and Unani) formulations and traditional medicine, draft guidelines on research related to disaster, national ethical guidelines for AIDS, bio-banking, dataset protection and research on mental health. Dr. Nandini is a member of Forum for Ethics Review Committees in Asia Pacific (FERCAP) region and Steering Committee of "Forum for Ethics Review Committee in India" (FERCI) and actively involved in functioning of ethics committees in various capacities. She is also a national and international SIDCER (Strategic Initiative for Development of Capacity in Ethics Review) surveyor of ethics committees for accreditation purpose. She is a member of international panel of President Obama's Commission for the Study of Bioethical Issues, Advisory Council of Indian Office of Drug Information Association, and other nationally important committees. Dr. Nandini K Kumar is one of the first Indian Fogarty Fellow graduate in Bioethics from the University of Toronto, Canada. All this has helped her to evolve strategies for bioethics education for various levels of researchers, faculty and ethics committee members in a span of 10 years under the aegis of ICMR (with Fogarty grant). A network among trainees has created secondary and tertiary waves of promoting awareness about bioethics among ethics committee members and investigators. After retirement in 2008 She was continuing activity in bioethics area as a NIH Grantee and initiated the first online PG Diploma course in bioethics in India under Fogarty funded ICMR-IGNOU joint initiative. Some of the trainees have become known in international circles. She is also a guide for postgraduate students, and consultant for bioethical issues and traditional medicine research in India and abroad. Her relationship with both institutions, Manipal University as Endowment Chair and Clinical Development Services Agency (CDSA) as Adjunct faculty added to her earlier experience in managing similar bioethics programs in ICMR would help in conduct of present program envisaged for this application easier. Having convened annual two-month course in Manipal University She has experienced that it provides a good environment for such activity. She is confident that along with the core group (Co-Is – Joseph Thomas, Stanley Mathew, Mary Mathew and K.L.Bairy) who had helped her to organize the two month program, workshops and seminars in bioethics, a strong foundation for bioethics education is already laid to set up a good Centre for Bioethics, under which the Bioethics Unit of UNESCO Chair in Manipal will work for dissemination of this education.



# About Resource Faculty

## Dr. Nalin Mehta:

Dr. Nalin Mehta is a Professor of Physiology at AIIMS, New Delhi. He is the First Indian civilian doctor to have wintered-over for 16 months at the Indian Research Base, Maitri in Antarctica as a member of the 12th Indian Scientific Expedition to Antarctica (Dec 1992-Apr 1994) for research.

After his return, he is selected by the Government of India, in November 1994, as an expert faculty member, deputed from AIIMS for a Government of India aided project, the B. P. Koirala Institute of Health Sciences (BPKIHS), a premiere medical college and hospital at Dharan, Nepal. He is instrumental in establishing the department of Physiology & the Clinical Physiology laboratories there. Back to AIIMS after his deputation, he is awarded the prestigious Fogarty International Bioethics Fellowship in 2002. On the successful completion of the fellowship, he is awarded Masters' degree in Bioethics from the University of Toronto Joint Centre for Bioethics. He is a well known name in the Bioethics circles, often an invited expert at various national and international forums. In addition, he serves as Chairperson on three, and as Member on a few other prominent Ethics Committees in the NCR of New Delhi.

Also an expert in the field of Medical Education he is a FAIMER fellow and very prominent resource person at the K L Wig Centre for Medical Education & Technology (CMET) at AIIMS, and very sought after and renowned expert for a host of national and international institutes and organizations. In addition, he is a Member of the Committee for Telemedicine at AIIMS and an expert on the SAARC Telemedicine Network Project. Till recently, he is the Associate Editor of the Indian Journal of Physiology and Pharmacology (IJPP), a prestigious indexed journal.

He is a nominated member of the National Health Information Network by the Ministry of Health & Family Planning, Government of India for formulating strategies for implementing the recommendations of the National Knowledge Commission.

His main areas of interest include Cellular & Molecular Reproductive Physiology, Yoga and Meditation based Lifestyle management, G-I Physiology & Nutrition, Research Methodology, Bioethics & Medical Education. He has several international and national publications including chapters in books.

## Dr. Kiran Katoch :

**Dr. Kiran Katoch**, is Former Director of National JALMA Institute for Leprosy and Other Mycobacterial Diseases( ICMR), Tajganj, Agra (UP), and is developer & In charge Model Rural Research Health unit at Ghatampur, Kanpur. She did MBBS (1974)and MD ( General Medicine)- 1979 from SMS Medical College, Jaipur;She has received several research trainings as a Talent Search Scholar of ICMR during 1975-78 on clinical haematology, genetics and cell biology, biostatistics, immunology, biochemistry and instrumentation etc. In her total research experience of more than 37 years; she worked for 34 years leprosy, about 12 years on TB, and other health problems of rural population. After completion of MD and various research trainings as a Talent Search Fellow of ICMR she is posted at Central JALMA Institute for Leprosy in 1979 and since then have been working at the Institute on various posts, rose from Research officer Director and Scientist G.

Dr Kiran Katoch has developed and implemented several extramural projects on leprosy and TB from WHO, GOI (CTB), GOI (CLD); DBT, ICMR etc. She has published over 160 publications on leprosy, TB ; in various reputed journals; 52 as first author/; remaining as co author. She has Presentations in approx 100 international and national conferences/ workshops/ symposia etc. Her major achievements include (i) Developed and evaluated several important regimens for treatment of leprosy , (ii) Contributions towards better understanding of systemic involvement in leprosy by investigations on cardiovascular, central nervous system and autonomic nervous system in leprosy cases; (iii) Evaluation of protective effect of vaccines against leprosy and TB. (iv) Played active part in the establishment of epidemiological studies on leprosy, tuberculosis at Ghatampur( Kanpur). This programme has been expanded and developed into a Model Rural Health Research Unit. Department of Health Research (DHR), Ministry of Health and Family Welfare. She has been member / chairperson of Research Advisory Committees in several states, ICMR, DHR etc.

Dr Kiran Katoch has received various **Awards and Honors** of repute like Dr. CGS Iyer Oration Award of ICMR, 1989; JALMA Trust Fund Oration Award of ICMR, 1994, VASVIK Award 2002 of Vividhlaxi Audhyogik Samshodhan Vikas Kendra , Sher e Kashmir Sheikh Mohammed Abdulla Oration Award 2009. She is fellow of National Academy of Sciences (India) and National Academy of Medical Sciences.

## About Resource Faculty

### Dr. Bharti Malhotra :

**Dr. Bharti Malhotra** is Senior Professor, Department of Microbiology, SMS Medical College, Jaipur & Nodal officer Advance Research & TB lab & Dean Faculty of Medicine Rajasthan University of Health Sciences, State lab coordinator IDSP. She is also head of State level Virology Laboratory of Department of Health Research, Ministry of Health and Family Welfare ( MoHFW), Govt of India which is one of the flagship programme of MoHFW.

Prof Bharati Malhotra did MBBS and MD (Microbiology) from SMS Medical College Jaipur and has 25 years of experience as a teacher and researcher. Major areas of her research pertain to tuberculosis and other mycobacterial diseases as well as medical virology. She is currently working on **International** projects including one on rapid diagnosis of MDR-TB and other CDC project on viral hemorrhagic fevers in collaboration with NIV, Pune etc. She has been Principal Investigator of projects from ICMR/ MoHFW on tuberculosis, virology. She has recently completed an extramural project on Grade I Virology laboratory of ICMR which has led to development of DHR laboratory. She developed and implemented an ICMR project on Molecular Epidemiology of Tuberculosis in slum areas of Jaipur. She is also a PI/ Co-PI of **national projects** from agencies including ICMR/ DHR eg. Identification of mutations in Epidermal Growth Factor Receptor [EGFR] using FNAC Cell Blocks in Non-Small Cell Lung Cancer [NSCLC] patients; Crohn's disease in India: A multicenter study from a country where intestinal tuberculosis as well as Johne's Disease is endemic. During the last five years she has published more 25 research papers in national and international journals. She has organised many workshops and CMEs related to HIV, TB and Virology. She is member of IAMM, HISICON and other professional bodies.



## About Resource Faculty

### Dr. Hemant Malhotra :

**Dr. Hemant Malhotra** is Senior Professor and Head, Department of Medicine, SMS Medical College, Jaipur. Dr Malhotra did his MBBS and MD ( Medicine) from SMS Jaipur, Specialized Course of 2 years duration from Tata Memorial Hospital Mumbai, other trainings at Cornell Medical centre and Memorial Sloan Kettering Cancer Centre, New York, USA.

In his more than 30 years of clinical teaching and research career, Prof Malhotra has worked at Bikaner and Jaipur. He has enormously contributed to the growth of Medical Oncology at SMS during the last 15 years and has been heading Medical Oncology Division at SMS Hospital since 2009. During his productive and well recognized research career Prof Malhotra has contributed to growth of Medical Oncology at National and International levels. He has been PI/Co-PI for several clinical trials. Besides having been a FRCP ( London), he is founder member of Indian Cooperative Oncology Network Member, Indian Council for Medical Research (ICMR) committee for National Cancer Treatment Guidelines on CML & Ca Buccal mucosa; Chairman, ICMR committee for National Cancer Treatment Guidelines on Multiple Myeloma; Member of several committees such Oncology Project Review Committee, ICMR, Medical Oncology Task Force, National Cancer Control Program, Government of India (GOI), , Scientific Advisory Committee, Institute of Cytology & Preventive Oncology, ICMR, GOI, Technical Expert to the Drug Controller of India on Oncology related new formulations and drugs, National Task Force of ICMR for Immuno-phenotyping of Hemato-lymphoid malignancies, Regional Representative from South East Asia to European Society of Medical Oncology (ESMO), Scientific Advisory Board, International Chronic Myeloid Leukemia Foundation (iCMLf), National Representative from India, International CML Foundation, and many others. He has been Joint Secretary of Ethics Committee of SMS and associated hospitals for several years. He has presented his work in more than 300 national/ international conferences and has published more than 60 papers in national and international journals.

**Ethical aspects of Bio-medical  
and Health Research  
(8<sup>th</sup>-9<sup>th</sup> April, 2017)**

**REGISTRATION FORM**

**(Xerox copies of the application can also be used)**

Name :  
Qualification :  
Designation :  
Department :  
Institution :  
Address :  
Contact Ph. No :  
E-mail ID :  
Place :  
Date :  
Concept Note :

Applicant's Signature

*Contact Dr. SudhanshuKacker, Workshop Convenor (Ph: 9983723535) for Registration related queries.*