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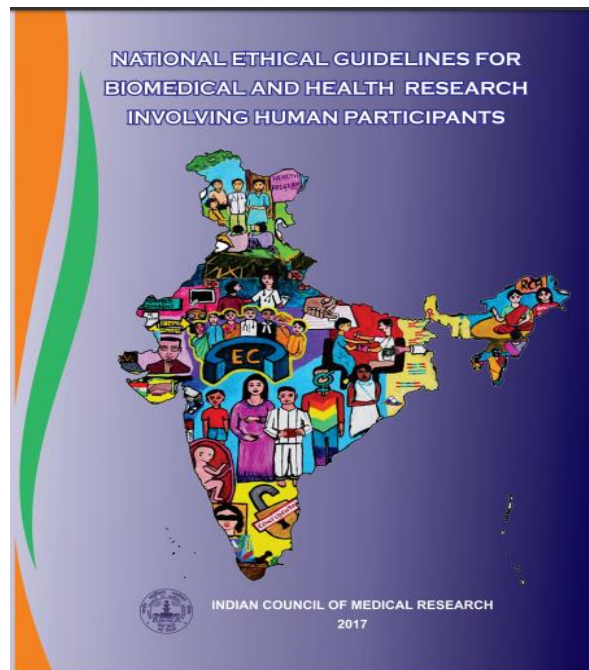
ICMR Training on Biomedical and Health Research Ethics

21-22 January 2020

At

B.R.D. Medical College, Gorakhpur

Training Report



Jointly Organised by:

ICMR-Regional Medical Research Centre, Gorakhpur

B. R. D. Medical College, Gorakhpur

ICMR Bioethics Unit, NCDIR, Bengaluru

An ICMR Training on Biomedical and Health Research Ethics was held on 21st and 22nd Jan 2020, at ICMR-RMRC, Gorakhpur, in collaboration with ICMR-NCDIR Bangalore and BRD Medical College, Gorakhpur.

Day I

21st Jan 2020

Inaugural Session:

The workshop commenced with the welcome and an introductory address by **Dr. Rajni Kant**, Director, ICMR-RMRC, Gorakhpur. He highlighted the importance of the safeguarding the rights and safety of research participants and adopting good ethical practices while doing research as well as following publication ethics while disseminating research findings. He welcomed all the dignitaries, faculty members and thanked NCDIR for conducting this workshop. Dr. Prashant Mathur, Director, ICMR-NCDIR, Bangalore shared his memory of being alumni of BRD Medical college and explained the importance of this kind of workshop. Dr. Ganesh Kumar, Principal, BRD Medical College, Gorakhpur; welcomed the delegates and guests and congratulated the participants for the workshop. Dr. Janardhan Mani Tripathi, Additional Director Health, Gorakhpur Division; Dr. Roli Mathur, Scientist 'F' & Head ICMR-Bioethics Unit, ICMR-NCDIR, Bangalore and Dr. Nandani K. Kumar, Former DDG, ICMR were also present at the occasion and appreciated this initiative. They also expressed happiness to see the huge response and enthusiasm of the participants.



The one and a half day workshop consisted of six technical sessions: National Ethics Guidelines, regulations, Ethics Committee, General Ethical Issues, responsible conduct of research and Informed Consent. The eminent faculty consisted of Dr.Roli Mathur, ICMR-NCDIR, Bengaluru; Dr. Bikash Medhi, PGIMER, Chandigarh; Dr.Medha Joshi, Tata Memorial Centre, Mumbai; Dr.Balu Venugopal, Department of Health Research, Dr. Nandini K. Kumar, Former DDG, ICMR; Dr. Prashant Mathur, ICMR-NCDIR and Dr. Lalita S. Savardekar, ICMR-NIRRH, Mumbai.

Session I

Dr.Bikas Medhi spoke about the new drugs and clinical trial rules 2019& GCP guidelines. He also touched upon various implications for clinical trials and its importance in Health Research.

Session II

Dr.Medha Joshi explained the composition, responsibilities and structure of ethical committees. She also touched upon the registration and accreditation as well as the role of DHR and CDSCO.



Dr.Balu Venugopal further elaborated the steps in Ethical Committee registration in DHR which are essential for those who want to get register their Ethical Committees.

There were also interactions with the participants on interesting case studies related to general ethical issues which were discussed by **Dr.Bikas Medhi** and **Dr.Medha Joshi**.



Session III

A short film on the history of Research Ethics was also shown on various aspects of good clinical and ethical practices.

Dr.Roli Mathur, elaborated in details about the National Ethical Guidelines developed by ICMR, which include each and every minute information required for ethical consideration. She added, a shorter version for quick reference has also been prepared.

Session IV

Dr.Nandani K. Kumar spoke on the various general ethical issues which should be taken into consideration including privacy and confidentiality, benefit-risk assessment, compensation, conflict of interest, community engagement, public health research and new technologies. She also defined the basic difference between public health research and public service by discussing few case studies.



All the sessions on Day I invoked the interests of the audience and there were a plethora of queries that were addressed by the experts.



Day 2

22nd Jan 2020

Session V

Dr. Prashant Mathur explained in detail about the major components of responsible conduct of research including publication ethics which involve falsification, fabrication, plagiarism, copyrights, IPR *etc.* He also spoke about various guidelines and other resources/committees like COPE and KMJE which can be helpful.

Session VI

Dr. Lalitha S. Savardekar deliberated a talk on informed consent and its various aspects such as elements of informed consent document, consent in crisis situation or when there is no one to give consent in emergency situation. She also discussed few case studies to give more clear idea about informed consent.



CONCLUSION

The complete event of ICMR Training on “Biomedical and Health Research Ethics” garnered positive response from all the participants. The workshop concluded with an address by **Dr. Rajni Kant**. He emphasized that Gandhi Ji always showed the path for protecting human dignity with truth, compassion and sympathy and even his holiness the Dalai Lama also talks about compassion; similarly, it is important to imbibe good ethical practices for responsible conduct of research and this workshop has indeed helped us to understand this mechanism. The workshop was attended by around 175 participants including faculty from BRD, Medical College, AIIMS, Gorakhpur, Faculty and Research Scholars from Gorakhpur University, Officials from DHR, RMRI, Patna and other institutions across the country. The program ended with a formal vote of thanks by **Dr. Hirawati Deval**, Scientist ‘D’ and Member Secretary of Institutional Human Ethical Committee (IHEC), ICMR-RMRC, Gorakhpur followed by National Anthem.



ICMR Training on Biomedical & Health Research Ethics

AGENDA

Day 1, 21st Jan 2020

(9:30 AM-5:00 PM)

9:30AM–10:00AM	REGISTRATION	
10:00 AM–10:30 AM (30min)	Welcome Opening Remarks	Dr Rajni Kant/Dr Ganesh Kumar Dr Prashant Mathur/ AD (Health)
Session I: Regulations		
10:30AM–11:10AM (40min)	New Drugs and Clinical Trials Rules 2019 & GCP Guidelines ➤ Implications for Clinical trials ➤ Implications for Biomedical and Health Research	Speaker: Dr Bikash Medhi
11:10AM–11:30AM	TEA BREAK	
Session II: Ethics Committees		
11:30AM–12:10PM (40min)	Ethics Committee ➤ Composition, Roles & responsibilities ➤ SOPs, Review, Archiving ➤ EC Registration & Accreditation (DHR & CDSCO)	Speaker: Dr Medha Joshi
12:10 PM – 12:20 PM (10min)	Steps in EC Registration with DHR	Speaker: Dr Balu Venugopal
12:20PM–01:30PM (1 hr 10 min)	Case Discussion on General Ethical Issues and Ethics Committee	Coordinators: Dr Medha Joshi Dr Bikash Medhi
01:30 PM–02.:30PM	LUNCH	
Session III: National Ethical Guidelines		
02:30PM–02:45 PM (15min)	History of Research Ethics (Video)	
02:45AM–03:25AM (40min)	Overview of Workshop and ICMR National Ethical Guidelines	Speaker: Dr Roli Mathur
03:25PM–03:45PM	TEA BREAK	
Session IV: General Ethical Issues		
03:45 Noon–04:30PM (45 min)	General Ethical Issues ➤ Privacy and Confidentiality ➤ Benefit-Risk Assessment ➤ Compensation ➤ Conflicts of Interest ➤ Community Engagement & Benefit Sharing ➤ Public Health Research ➤ New Technologies	Speaker: Dr Nandini K. Kumar
04:30PM–05:00 PM	General Discussion & Closure	

DAY 2: 22nd Jan 2020 (9:30 AM – 1:00 PM)



9:30 AM – 10:00 AM	Attendance/ Recap of Day 1	
Session V: Responsible Conduct of Research		
10:00 – 10:30 AM (30 min)	Responsible Conduct of Research	Speaker: <u>Dr Prashant Mathur</u>
Session VI: Informed Consent Process		
10:30 AM – 11:10 AM (40 min)	Informed Consent Process <ul style="list-style-type: none">➤ Elements of Informed Consent Document (ICD)➤ Consent and Assent requirements➤ Discussion/ Group Activity	Speaker: <u>Dr Lalita S Savardekar</u>
11:10 AM – 11:30 AM	TEA BREAK	
11:30 AM – 12:30 PM	Case Discussion on Informed Consent Process	Coordinators: <u>Dr Lalita S Savardekar</u> <u>Dr Nandini K Kumar</u>
12:30 PM – 01:00 PM	General Discussion & Closure	

CHIEF GUEST

Dr. Janardhan Mani Tripathi, Additional Director Health, Gorakhpur Division

SPEAKERS

1. Dr. Nandani K Kumar, Former DDG, ICMR
2. Dr. Prashant Mathur, Director, ICMR-NCDIR, Bangalore
3. Dr. Roli Mathur, Scientist F & Head, ICMR- Bioethics Unit, ICMR-NCDIR, Bangalore
4. Dr. Bikash Medhi, PGIMER, Chandigarh
5. Dr. Medha Joshi, Tata Memorial Centre, Mumbai
6. Dr. Balu Venugopal, Department of Health Research
7. Dr. Lalita S Savardekar, ICMR-NIRRH, Mumbai.

ORGANISERS

1. Dr. Rajni Kant, Director, ICMR-RMRC, Gorakhpur
2. Dr. Roli Mathur, Scientist F & Head, ICMR-Bioethics Unit, ICMR-NCDIR, Bangalore
3. Dr. Ganesh Kumar, Principal, BRD Medical College

COORDINATORS

1. Dr. Hirawati Deval, Scientist D & Member Secretary, Institutional Human Ethics Committee (IHEC), ICMR-RMRC, Gorakhpur
2. Dr. Roli Mathur, Scientist F & Head, ICMR-Bioethics Unit, ICMR-NCDIR, Bangalore
3. Dr. Jamal Haider, Associate Professor, Department of Pharmacology, BRD Medical College, Gorakhpur

Report Compiled by

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