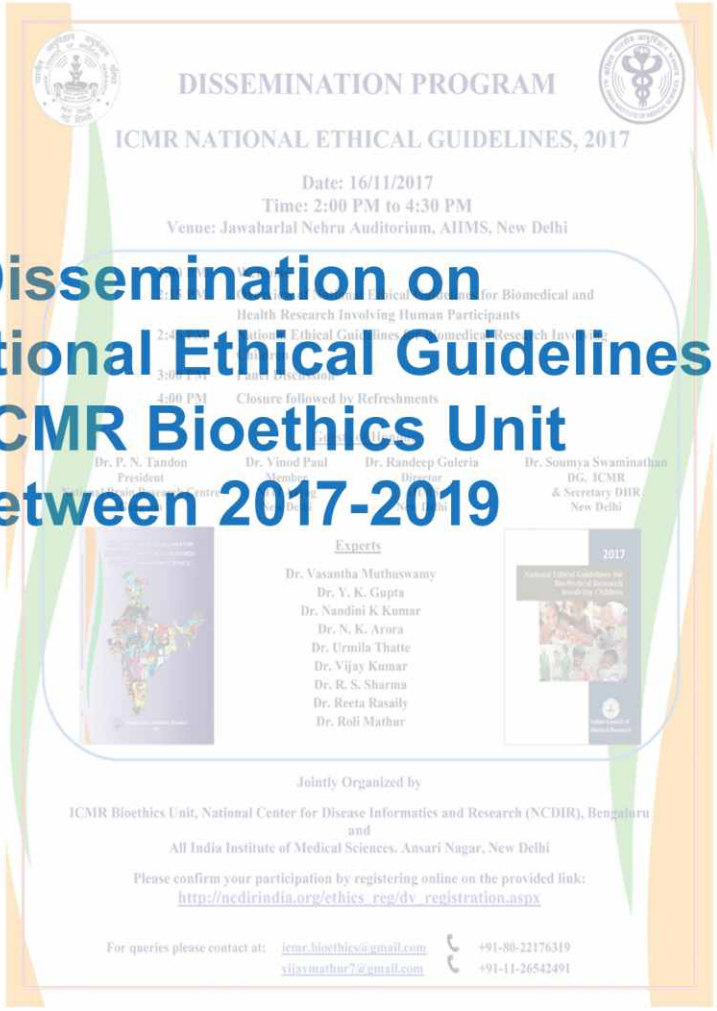
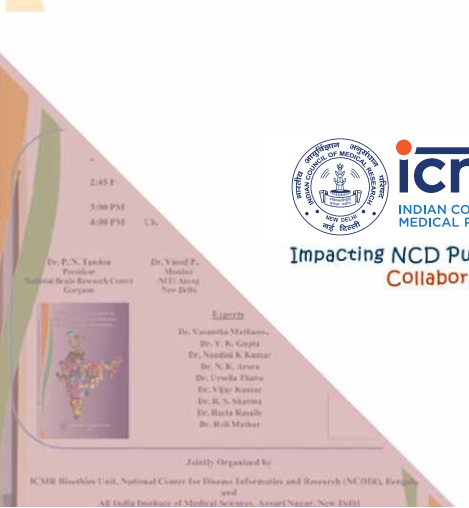


Dissemination on ICMR National Ethical Guidelines by ICMR Bioethics Unit Between 2017-2019

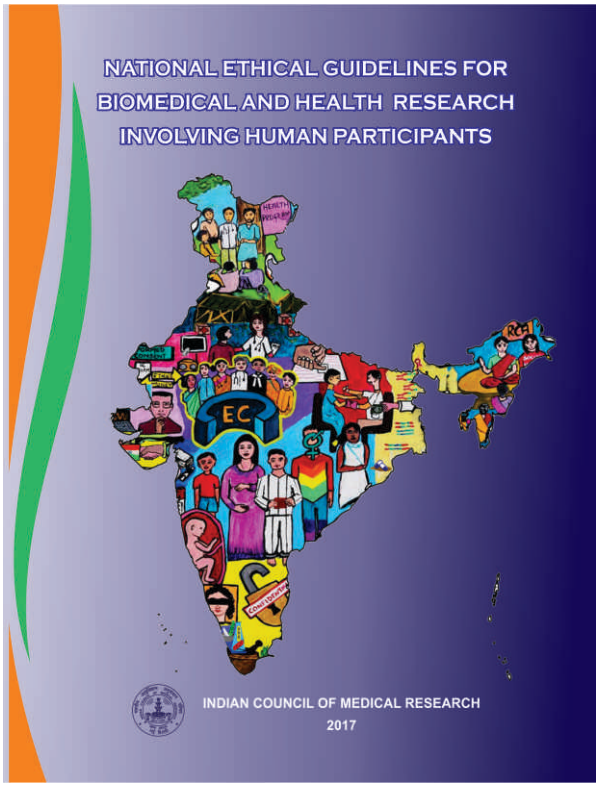


ICMR INDIAN COUNCIL OF MEDICAL RESEARCH | NCDIR NATIONAL CENTRE FOR DISEASE INFORMATICS AND RESEARCH

Impacting NCD Public Health Actions and Policies

Collaborate Innovate Inspire

Dissemination on ICMR National Ethical Guidelines by ICMR Bioethics Unit Between 2017-2019



INDIAN COUNCIL OF MEDICAL RESEARCH | NATIONAL CENTRE FOR DISEASE INFORMATICS AND RESEARCH

Impacting NCD Public Health Actions and Policies

Collaborate Innovate Inspire

ICMR BIOETHICS UNIT

National Centre for Disease Informatics and Research

(Indian Council of Medical Research), Bangalore

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FOREWORD BY DIRECTOR, NCDIR, BANGALORE

I am pleased to present the consolidated report of the dissemination and training programs on ICMR National Ethical Guidelines conducted across the country during 2017-2019. It is very encouraging to see that 6751 participants including ethics committee members, students (medical/non-medical), nurses, clinicians, faculty, scientists, lawyers and others from across the country covering 649 institutes benefitted from these programs. The dissemination programs discussed all the sections in the guidelines, resolved several queries and was able to encourage better transparency in the ethical review process. Participants from various disciplines of health research benefitted from dissemination cum training programs.

Dissemination programs of such comprehensive nature was planned and implemented for the first time in the country to create awareness about ethical standards and to improve the quality of health research outcomes. With the inclusions of clauses to govern biomedical and health research in the recently notified New Drugs and Clinical Trials Rules 2019, all the stakeholders are required to follow the ICMR National Ethical Guidelines for Biomedical and Health Research Involving Human Participants, 2017. Therefore, driven by the need for greater outreach and more such programs to cover the entire population of our country, many such programs are being planned across the country by the ICMR Bioethics Unit, NCDIR, Bangalore.

We would encourage researchers, academicians, ethics committee members, institutional heads, funding agencies and other key stakeholders to spread awareness on need for ethical conduct of biomedical and health research.

January, 2020
Bangalore

Dr Prashant Mathur
Director,
ICMR-NCDIR, Bangalore

MESSAGE BY CHAIRPERSON, ETHICS ADVISORY COMMITTEE

The Ethical Guidelines developed by the Indian Council of Medical Research (ICMR) for biomedical research involving human subjects/participants in 2000/2006 are looked upon by stakeholders all over the country, such as researchers, students (UG/PG), faculty members, ethics committees and regulators as gold standard for protection of safety and welfare of the research participants in this country. The latest revision of the National Ethical Guidelines for Biomedical and Health Research Involving Human Participants was released by ICMR in October 2017 after wide national and international consultations. Since then continued efforts are being made to disseminate the guidelines not only to the biomedical and health researchers, but also to NGOs, industry, and various other relevant stakeholders.

During 2017 – 2019, 12 dissemination and training programs were conducted across the country to reach out to maximum possible stakeholders. A series of programs were held at AIIMS, New Delhi; PGIMER, Chandigarh; Sri Ramachandra Medical College, Chennai; AIIMS, Bhubaneswar; AMCMET Medical College, Ahmedabad; Andhra Medical College, Visakhapatnam; Amrita Institute of Medical Sciences, Kochi; Gauhati Medical College, Guwahati; Gadag Institute of Medical Sciences (GIMS), Gadag; Kalinga Institute of Medical Sciences (KIMS), Bhubaneswar, Jawaharlal Institute of Postgraduate Medical Education & Research (JIPMER), Puducherry and St. John's Medical College, Bangalore. The four programs were held in collaboration with Clinical Development Services Agency (CDSA), Translational Health Science and Technology Institute (THSTI), Faridabad and another four programs were supported by Department of Health Research (DHR), New Delhi.

Overview of the ICMR National Ethical Guidelines for Biomedical and Health Research Involving Human Participants, 2017 and National Ethical Guidelines for Biomedical Research Involving Children, 2017 and National Guidelines for Stem Cell Research were presented in the programs followed by panel and open house discussion. The participants got an opportunity to interact with the experts, the panel discussions were interactive and the experts responded to the questions raised by the participants. The interaction included real-life ethical issues and scenarios encountered during the conduct or review of the biomedical and health research. It was overwhelming to see the enthusiasm of the participants. It was also realised that many stakeholders are still unaware about the National Ethical Guidelines and these programs helped to create awareness amongst them as well. These sessions were planned with the aim of spreading awareness about ethical conduct of biomedical and health research across the country so that the dignity, rights, safety and well-being of the human research participants are protected.

Many more such programs are needed to cover the entire biomedical and health research sector of the country. The enthusiasm of the participants and the growing demand for more of such programs is a welcome trend being witnessed and the effort taken by the ICMR in this regard is praiseworthy.

January, 2020
Bangalore

Dr Vasantha Muthuswamy
Chairperson,
Ethics Advisory Committee
ICMR-NCDIR, Bangalore

ACKNOWLEDGEMENTS

It gives me immense pleasure to thank the participants and institutions that contributed towards the successful organization and conduct of Dissemination programs at various locations across the country. I would like to thank Prof. Balram Bhargava, DG, ICMR and Secretary, DHR for his encouragement and support and sincere thanks to Dr. Soumya Swaminathan, Former DG, ICMR and Secretary, DHR and Dr. Gagandeep Kang, Executive Director, THSTI whose interest and immense support contributed greatly to the development and delivery of these programs. My special thanks to all the members of the Ethics Advisory Committee, ICMR-NCDIR, for their valuable guidance.

Special thanks are extended to the Clinical Development Services Agency (CDSA), Translational Health Science and Technology Institute (THSTI), Faridabad, Haryana for organizing the four dissemination programs conducted at Ahmedabad, Visakhapatnam, Kochi and Guwahati. I am particularly grateful to Dr. Sucheta Banerjee Kurundkar for facilitating the conduct and to all the faculty members for sharing their knowledge, experiences, and perspectives during the program. I would like to thank Department of Health Research (DHR) for providing funding for Dissemination and Training Programs on ICMR National Ethical Guidelines.

I would like to acknowledge the proactive support by the local organizers, Dr. Y K Gupta and Dr. Vijay Prakash Mathur at AIIMS, New Delhi; Dr. Bikash Medhi, PGIMER, Chandigarh; Dr. Banu Rekha V (ICMR-NIRT) and Dr. T. Santha Devi, Sri Ramachandra Medical College, Chennai; Dr. Arvind Kumar Singh, AIIMS, Bhubaneswar for ICMR organized programs and also local organizers at AMCMET Medical College, Ahmedabad; Andhra Medical College, Visakhapatnam; Amrita Institute of Medical Sciences, Kochi; Gauhati Medical College, Guwahati for CDSA facilitated programs.

I would also like to thank Dr. Ravindra PN, Gadag Institute of Medical Sciences (GIMS), Gadag; Dr. S K Rath and Dr. Soumya Mishra, KIMS, Bhubaneswar; Dr. Rakesh Aggarwal and Dr. Jayanthi M, JIPMER, Puducherry and Dr. Karuna Rameshkumar and Dr. Jayanthi Savio, St. John's Medical College, Bangalore for DHR supported programs.

I would like to thank Dr. Prashant Mathur, Director, NCDIR, Bangalore for his continuous guidance and support. I thank Dr. Kalyani Thakur who supported me in analysis, writing and publication of this report. I also thank all members of ICMR Bioethics Unit, NCDIR who were involved in organizing the events and especially Dr. Rajib Kishore Hazam, and Mr. Bhyregowda.

This was the largest ever program in India on ICMR National Ethical Guidelines and we hope that it was able to fulfil the mandate of reaching out to a large number of stakeholders and creating awareness about the ethical requirements for biomedical and health research.

January, 2020
Bangalore

Dr Roli Mathur
Scientist F and Head,
ICMR Bioethics Unit,
ICMR-NCDIR, Bangalore

1. EXECUTIVE SUMMARY

The Indian Council of Medical Research (ICMR) issued the first **"Policy Statement on ethical considerations involved in research on human Subjects"** in 1980. The ethical guidelines were prepared in 2000 and revised in 2006, with the latest revision in 2017 as ICMR "**National Ethical Guidelines for Biomedical and Health Research Involving Human Participants"**. At the same time **'National Ethical Guidelines for Biomedical Research Involving Children'** was also released.

Even though ICMR Ethical Guidelines were present way back since 1980, their wider dissemination is required in order to create awareness about the ethical requirements for biomedical and health research.

Upon the release of the National Ethical Guidelines, ICMR planned a series of Dissemination cum Training Programs which were held across the country. This is the largest ever initiative in the country in the area of research ethics so far to sensitize the various stakeholders about the National Ethical Guidelines.

Participants from various medical colleges, biomedical research institutions, paramedical institutes, universities, colleges, industry personnel, etc. were identified and contacted through email, online advertisement, social media, brochures etc. and encouraged to participate. There was no registration fee to attend the program. The attendees were required to e-register and were given e-Certificates of attendance after confirming attendance during the program.

During the program, key highlights of ICMR National Ethical Guidelines were shared and an expert panel addressed questions from the audience to clarify doubts. Details could be shared with 6751 people including Ethics Committee members, students (medical/ non-medical), nurses, clinicians, faculty, scientists, lawyers and other interested stakeholders. Within a period of 2017-2019, ICMR Bioethics Unit, NCDIR was able to conduct 12 programs, 4 of these programs were supported by ICMR; and another 4 were supported by Clinical Development Services Agency (CDSA) during the year 2017-2018 and the last 4 dissemination and training programs were organized with funding support received from Department of Health Research (DHR) in the year 2019. Participants from 24 States/ Union territories, covering around 649 institutes from the country benefitted from these programs. The outreach programs were successful as the dissemination reached to the large number of expected stakeholders involved in biomedical and health research.

2. INTRODUCTION

The ICMR "National Ethical Guidelines for Biomedical and Health Research Involving Human Participants, 2017" have been developed after long and careful deliberations with experts and stakeholders, from various backgrounds across the country, who have carefully dealt with difficult topics, to prepare the document in line with National as well as International guidelines, frameworks and regulations. The revised guidelines are not only an update of the earlier guidelines but also address emerging ethical concerns.

The ICMR National Ethical Guidelines was released by Shri JP Nadda, Former Minister of Health and Family Welfare and Smt. Anupriya Patel, Former Minister of State for Health and Family Welfare in the presence of various other dignitaries, Dr. Soumya Swaminathan, Former DG ICMR and Secretary DHR, Dr. P N Tandon, Former Chairperson, Central Ethics Committee on Human Research (CECHR) and Dr. Henk Bekedam, Country Representative, WHO-WR on 12th October, 2017 at ICMR Headquarters, New Delhi. ICMR National Ethical Guidelines for Research Involving Children have also been prepared and released on the same day and guides research on children.

There are 12 sections in the guidelines and that includes new sections such as Responsible Conduct of Research, Informed Consent Process, Vulnerability, Public Health Research, Social and Behavioral Sciences Research for Health, Biological materials, Biobanking and Datasets and Research during Humanitarian Emergencies and Disasters. Many new issues have been added up as subsections e.g. sexual minorities (LGBT), multicentric studies, research using datasets etc. The section on ethics review process has been elaborated upon to help the ethics committees in improving their functions. The guidelines also highlight the need for capacity building in the area of ethics in order to improve the ethical conduct of research. [1,2,3]

In spite of having ethical guidelines since 1980, it was realized that, the guidelines had not been able to reach all the required or interested stakeholders. Understanding the need, ICMR Bioethics Unit planned dissemination programs for National Ethical Guidelines for Biomedical and Health Research Involving Human Participants, 2017 and National Ethical Guidelines for Biomedical Research Involving Children and training programs for relevant stakeholders across the country.

Dissemination and training programs were organized across the country for relevant stakeholders involved in biomedical and health research such as researchers, ethics committee members, students, faculty, nurses, clinicians, scientists, lawyers, representatives from pharmaceutical industries, representatives from governmental as well as nongovernmental organizations. Four of the programs were funded by ICMR and coordinated by National Centre for Disease Informatics and Research (ICMR-NCDIR) and another four of the dissemination programs were conducted with funding support from Clinical Development Services Agency (CDSA), under Translational Health Science and Technology Institute (THSTI), Faridabad during the year 2017-2018. Another 4 dissemination and training programs were organized in 2019 with funding support received from Department of Health Research (DHR).

Stakeholders from various medical colleges, biomedical research institutions, paramedical institutes, universities, colleges, industry personnel, etc. were contacted and informed about the details of the program via email, phone, posters, pamphlets, visits to the nearby institutions by the local organizing team as well as using the social media platforms (Facebook, Twitter etc). An online portal was developed for registration of the participants and the link for online registration was posted on the websites of ICMR Headquarters, New Delhi; NCDIR, Bangalore; CDSA and local organizing institutes for wider outreach. For CDSA, THSTI supported programs, similar web portal developed by CDSA and also posted on ICMR website. To encourage maximum participation, the registration was made free of cost and spot registrations were also facilitated for interested participants. The participants were provided with an information brochure highlighting the salient features of the ICMR National Ethical Guidelines. The attendees were given e-Certificates of participation after confirming attendance during the program.

Each dissemination event was conducted and coordinated by an eminent panel of experts from biomedical and health research ethics background who were part of the group that drafted and reviewed the guidelines. The sessions included overview of the ICMR National Ethical Guidelines followed by panel discussion. Key issues related to the ICMR National Ethical Guidelines were highlighted during the program and the expert panel addressed questions from the audience. The open house discussions enabled interaction of participants with the experts to clarify the concerns related to various ethical aspects of biomedical and health research. During 2017-2019, 12 dissemination/training programs were conducted and total 6751 stakeholders were informed and briefed about ethical guidelines. This was the largest initiative in India to reach out to the public with the goal to create awareness of the ethical requirements for biomedical and health research and thereby to improve protection of the dignity, rights, safety and well-being of human research participants.

Figure 1. Dissemination programs in various parts of the country

NEW DELHI

CHANDIGARH

CHENNAI

BHUBANESWAR

AHMEDABAD

VISAKHAPATNAM

KOCHI

GUWAHATI

GADAG

BHUBANESWAR

PUDUCHERRY

BENGALURU

3. AIM/ PURPOSE

In order to create awareness about the ICMR National Ethical Guidelines for Biomedical and Health Research Involving Human Participants amongst all the stakeholders such as clinicians, researchers, ethics committee members, students, nurses as well as faculty involved in biomedical and health research, a series of 12 dissemination/training programs were planned across the country.

The main purpose of the dissemination programs:

a) to share the information regarding ICMR National Ethical Guidelines with relevant stakeholders, and

b) to promote the ethical conduct of biomedical and health research in the country.

4. METHODOLOGY

A total of 12 programs (half-day/one-day/two-day) was conducted to update and sensitize the stakeholders about the ICMR National Ethical Guidelines across the country. Each dissemination program targeted participation of approximately 500 to 1000 participants and 50-100 participants for training programs from medical colleges, research institutions and other interested stakeholders from surrounding areas drawing from various backgrounds including students, faculty, nurses, researchers, pharmacy, dental and other allied para medical staff and ethics committee members who are engaged in biomedical research or in the review of such research studies.

a. Selection of Sites:

These programs were held across the country over a period of two years (November, 2017 to Sept, 2019). ICMR-NCDIR supported programs were held at AIIMS, New Delhi; PGIMER, Chandigarh; Sri Ramachandra Medical College, Chennai and AIIMS, Bhubaneswar and CDSA, THSTI supported programs held at AMCMET Medical College, Ahmedabad; Andhra Medical College, Visakhapatnam; Amrita Institute of Medical Sciences, Kochi and Gauhati Medical College, Guwahati. DHR supported programs were held in the year 2019 at GIMS, Gadag; KIMS, Bhubaneswar; JIPMER, Puducherry and St. John's Medical College, Bangalore.

b. Participants:

All interested stakeholders involved in biomedical and health research from the given city or nearby areas were provided opportunity to register and attend the program, such as faculty, clinicians, researchers, ethics committee members, students (medical/non-medical/paramedical), UG/PG/Post-Doctoral/Senior Residents, nurses, dental, pharmacy, physiotherapy, traditional medicine, biotechnology, social sciences and other allied sciences, NGOs, sponsors, regulators, patient representatives etc.

c. Registration:

An online portal was developed for registration of the participants to the programs. The link to the online registration portal was posted on relevant websites to ensure maximum participation and outreach. Registration was made completely free of cost and also made available on-spot. Information with respect to name, designation, affiliation, participant profile etc., was collected from the participants during

registration. Brochures and banners were designed with registration link, contact information and complete details of the program and posted on the websites. Posters were also prepared to share contents of ICMR National Ethical Guidelines (Annexure – a).

d. Prior arrangements:

Prior to conduct of these programs, widespread publicity was given and a brochure with details was designed for each program. Relevant stakeholders were contacted and informed via email, phone, posters, pamphlets, Facebook, Twitter, etc. and also by personal visit to the nearby institutions by the local organizing team. ICMR Bioethics Unit also wrote letters to various medical colleges and research institutions to publicize the program.

A stall to display the ICMR National Ethical Guidelines and a counter for purchase of guidelines was also set up for interested stakeholders. Posters of ICMR National Ethical Guidelines were displayed at the venue of the program.

The registered participants were provided with an information brochure/pamphlet highlighting the salient features of the ICMR National Ethical Guidelines (Annexure – b). They were given e-Certificates of participation after confirming attendance during the program.

e. Conduct:

Scientific content and conduct of program were led by the ICMR Bioethics Unit, NCDIR, Bangalore. The local organizers played an important role in all local arrangements and in assisting ICMR Bioethics Unit to reach out to a very large number of stakeholders from the local regions and in the successful conduct of the events.

The program for Dissemination of ICMR National Ethical Guidelines was implemented as a half day program. Dissemination cum Training programs/Training programs were organized for one day or two day depending upon the request received from the local organizers. A panel of experts with experience in biomedical and health research ethics coordinated and conducted the sessions at each centre. The Ethics Advisory Committee, ICMR-NCDIR played an important role in planning, selection of venue and implementation of these programs.

An overview of the National Ethical Guidelines for Biomedical and Health Research Involving Human Participants and National Ethical Guidelines for Biomedical Research Involving Children was provided. An overview of the National Guidelines for Stem Cell Research was also provided in CDSA, THSTI supported programs.[1,4,5]

An Open House Discussion was organized which enabled active discussions and Question-Answer session in order to clear the doubts of participants on the newly published guidelines. During the training programs, various case studies (related to EC review challenges, informed consent process, research involving vulnerable participants, public health research and research during emergencies and disaster, etc.) were presented and discussed in detailed with the participants. The participants got an opportunity to interact with the experts and receive the latest updates.

5. RESULTS

a. Geographic Coverage

The locations for the programs were selected with care to make sure that nationwide outreach is attained. The renowned institutes in the respective areas were selected as host institutions for the conduct of these programs. This ensured ease of access of the locations for participants to attend the program. Details of the programs conducted at various places across the country are given in Table 1.

In order to study the pattern of topographical participation, the data was analysed for state-wise participation which included 6751 participants. The region/state the institution of the participant belongs to, were taken to consideration, and as per analysis, 649 institutes representing 21 states and 3 union territories attended the dissemination program. It was also observed that maximum participation was seen from the state of Gujarat, New Delhi and Tamil Nadu. 7 programs were organized at Govt institutions and 5 were held at private institutions.

Two international participants attended the program. The Editor in Chief of The BMJ, London, UK attended the dissemination program held at AIIMS, New Delhi on 16th November, 2017 and one Project Coordinator from John Hopkins University, Baltimore, USA attended the program held at Sri Ramachandra Medical College, Chennai on 7th February, 2017.

Table 1: Details of Dissemination Programs conducted across the country

Dissemination Programs organized during 2017-2018				
ICMR – NCDIR				
Sl. No.	**Date**	**Venue**	**Panelist**	**No. of Participants**
1.	November 16, 2017	All India Institute of Medical Sciences (AIIMS), New Delhi	Dr. Vasantha Muthuswamy Dr. Y K Gupta Dr. N K Arora Dr. Vijay Kumar Dr. Roli Mathur Dr. Urmila Thatte Dr. Reeta Rasaily	650
2.	December 14, 2017	Postgraduate Institute of Medical Education and Research (PGIMER), Chandigarh	Dr. Nandini K Kumar Dr. Roli Mathur Dr. Bikash Medhi Dr. Naveen Sankhyan Dr. Nalin Mehta Dr. Medha Joshi Mr. B.K. Samantaray Dr. Suvasini Sharma Dr. Reeta Rasaily	1201
3.	February 7 2018	Sri Ramachandra Medical College, Chennai	Dr. Nandini Kumar Dr. Urmila Thatte Dr. Nalin Mehta Dr. Bikash Medhi Dr. P. Paul Kumaran Dr. Geeta Jotwani Dr. Roli Mathur	939
4.	February 17, 2018	All India Institute of Medical Sciences (AIIMS), Bhubaneswar	Dr. Nandini K Kumar Dr. Sanghamitra Pati Dr. Nalin Mehta Dr. Bikash Medhi Dr. M. Jeeva Sankar Dr. Roli Mathur	642
			Total Participants	**3432**

ICMR-NCDIR & CDSA				
Sl. No.	**Date**	**Venue**	**Panelist**	**No. of Participants**
1.	November 30, 2017	AMCMET Medical College, Ahmedabad	Dr. Vasantha Muthuswamy Dr. Nandini K Kumar Dr. Alka Sharma Dr. Roli Mathur Dr. N K Mehra	669
2.	December 21, 2017	Andhra Medical College, Visakhapatnam	Dr. Vasantha Muthuswamy Dr. Nandini K Kumar Dr. Alka Sharma Dr. Roli Mathur Mr. Bangarurajan	322
3.	February 22, 2018	Amrita Institute of Medical Sciences, Kochi	Dr. Nandini K. Kumar Dr. Roli Mathur Dr. Bikash Medhi Dr. P. Paul Kumaran Dr. R. Krishna Kumar	752
4.	March 8, 2018	Gauhati Medical College, Guwahati	Dr. Nandini K. Kumar Dr. Roli Mathur Dr. Bikash Medhi Dr. Suvasini Sharma Dr. Santanu K. Tripathi Dr. Gayatri Bezboruah	785
			Total Participants	**2528**

Dissemination Programs organized during 2019				
ICMR-NCDIR & DHR				
Sl. No.	**Date**	**Venue**	**Panelist**	**No. of Participants**
1.	March 7, 2019	Gadag Institute of Medical Sciences (GIMS), Gadag	Dr. Vasantha Muthuswamy Dr. Nandini K Kumar Dr. Urmila Thatte Dr. Padmaja Marathe Dr. S.L. Hoti Dr. Rajib K Hazam Dr P. N. Ravindra	259
2.	June 28–29, 2019	Kalinga Institute of Medical Sciences (KIMS), Bhubaneswar	Dr. Vasantha Muthuswamy Dr. Nandini K Kumar Dr. Urmila Thatte Dr. Padmaja Marathe	245
3.	September 16–17, 2019	Jawaharlal Institute of Postgraduate Medical Education and Research (JIPMER), Puducherry	Dr. Vasantha Muthuswamy Dr. Rakesh Aggarwal Dr. Nandini K Kumar Dr. Bikash Medhi Dr. P Paul Kumaran Dr. Shubha Kumar Dr. M Jayanthi Dr. Reba Kanungo Dr. R. Raveendran Dr. Narayanan P Dr. C Suthakaran Dr. Prasanth Penumadu Dr. Prasanth Ganesan Dr. Medha R Dr. S Sandhiya	80
4.	September 19–20, 2019	St. John's Medical College, Bangalore	Dr. Vasantha Muthuswamy Dr. Nandini K Kumar Dr. Urmila Thatte Dr. Bikash Medhi Dr. Pratibha Pereira Dr. Karuna Rameshkumar Dr. Prem Pais Dr. Johnson Pradeep Dr. Manjulika Vaz Dr. Arvind Kasthuri Dr. Savitha D	207
			Total Participants	**791**
			Grand Total	**6751**

b. Institutes/ organizations participated in the Dissemination Programs:

The information provided by the participants regarding their profile and affiliation during registration were used for the analysis. The participants belonged to 471 Educational institutions (72%), 37 Industries - Pharma/ CRO/ SMO/ Devices/ Others (6%), 56 Government agencies (9%), 9 NGOs (2%) and 21 other related organizations – not specified (11%). Out of 471 Educational institutes (Medical Colleges/ Hospitals/ Research Institutes/ Universities), approximately 235 institutes were public sector organizations and 236 were from private sector. The Geographical distribution of institution wise participation in various parts of the country are given in Figure 2. Details of the institutions represented by the participants are given in Table 2. A pie chart demonstrating the distribution of institute's profiles are given in Figure 3.

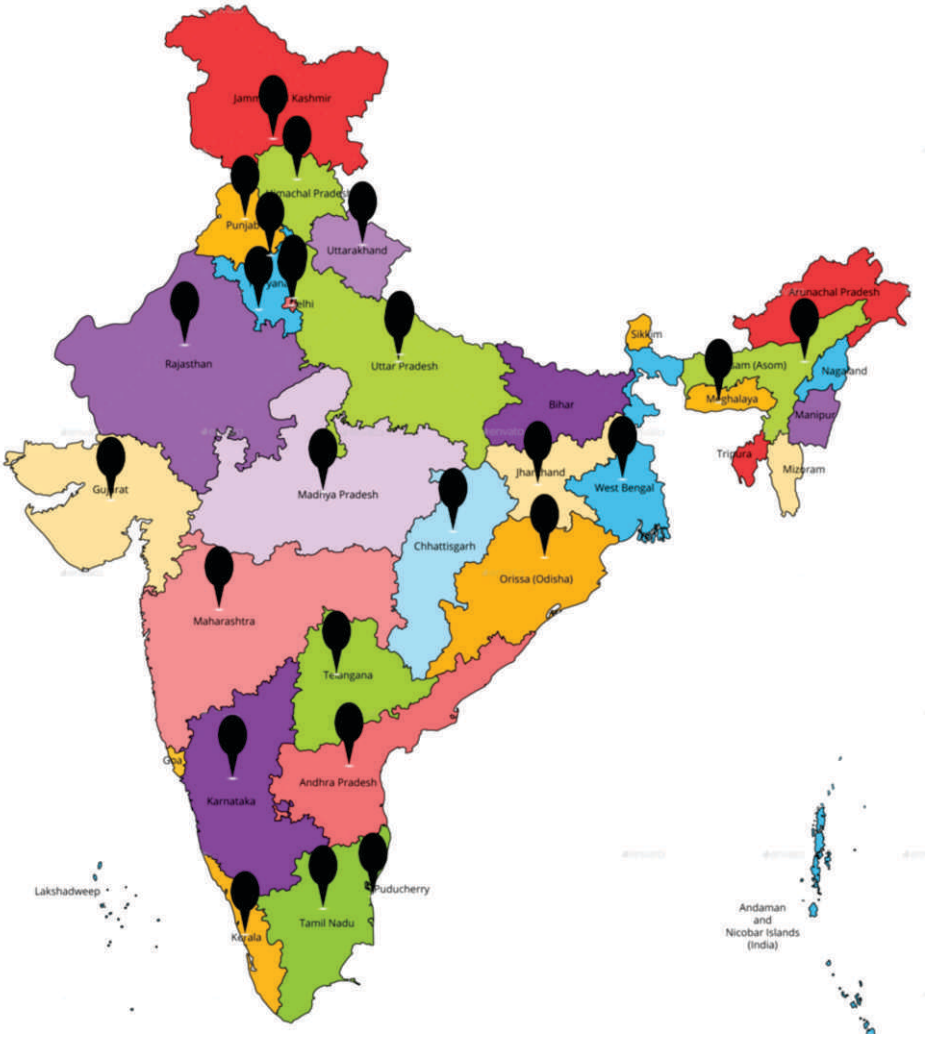


Figure 2. Geographical distribution of the institutions (of participants) in various parts of the country

The data analysis shows that people from various backgrounds attended the dissemination and training programs conducted across the country. Out of 6751, 590 ethics committee members (9%) such as Basic Medical Scientist, Clinicians, Pharmacologists, Legal Experts, Social Scientists, Philosopher / ethicist / Theologian, Lay person attended the program. 16 Chairperson/Co-chairs and 63 Member Secretaries / Joint Secretaries of the Ethics Committees also participated in the programs conducted at various places across the country. The Faculty / Scientist group comprised of Clinicians, Biomedical, Dental, Pharmacy, AYUSH and Others and represented 1456 (24%) of the total participants. The student group who participated in various programs included UG/PG/Ph.D/ Post Doc from Medical, Non-medical, Dental, Pharmacy, AYUSH or others and constituted 42% of the total participants.

The dissemination programs could cover 6751 participants (students, faculty, scientists, ethics committee members, etc.) from 649 Institutes (public, private, industry, govt agencies, NGO, etc.) across the country (Tables 2, 3 & 4). The summary of the participants/institutes is given in Table 5.

Table 5: Summary of Dissemination Programs

S. No.	Participants/ Institutes	ICMR-NCDIR	ICMR – NCDIR & CDSA	DHR & ICMR - NCDIR	Total Number
1.	Participants	3432	2528	791	**6751**
2.	EC Members	191	160	239	**590**
3.	Faculty/Scientists	960	496	335	**1791**
4.	Students	1650	981	179	**2810**
5.	Institutes	268	214	167	**649**

Summary of the eight dissemination programs are given below:

1. AIIMS, New Delhi

The first dissemination program on ICMR National Ethical Guidelines was held at AIIMS, New Delhi on 16th November, 2017 after the release of guidelines on 12th October, 2017. The program was inaugurated by Dr. PN Tandon in the presence of Dr Soumya Swaminathan, the Former, DG ICMR and Secretary, DHR; Dr. Vinod Paul, Member NITI Aayog and Dr Randeep Guleria, Director AIIMS. The half day program was attended by 650 participants from 83 institutions. 30 ethics committee members, 193 Faculty / Scientists and 357 Students (Medical / Non-medical) as well as people from various other backgrounds such as representatives from Industry, NGO, Govt officials, etc. attended the program.

2. AMC MET Medical College, Ahmedabad

The second dissemination program was conducted at AMC MET Medical College, Ahmedabad on 30th November, 2017. It was attended by 669 participants from 88 various organizations representing 76 EC members, 86 Faculty/ Scientists, 119 Students (Medical/Non-medical).

3. Post Graduate Institute of Medical Education and Research (PGIMER), Chandigarh

The third dissemination program was organized at Post Graduate Institute of Medical Education and Research (PGIMER) Chandigarh on 14th December 2017. A total of 1201 participants from 106 institutes attended the program. The stakeholders included 41 EC members, 270 Faculty/Scientists and 627 Students (Medical/Non-medical).

4. Andhra Medical College, Visakhapatnam

The fourth in the series was organized at Andhra Medical college, Visakhapatnam on 21st December, 2017 jointly by ICMR-NCDIR and CDSA. 322 participants representing 17 EC members, 99 Faculty/Scientists, 114 Students along with other stakeholders from 28 different institutions attended the dissemination program.

5. Sri Ramachandra Medical College and Research Institute, Chennai

ICMR-NCDIR organized its fifth dissemination program at Sri Ramachandra Medical College and Research Institute, Chennai on 7th February, 2018. 939 participants from 43 institutions attended the program. Total 95 EC members, 267 Faculty/Scientists and 395 Students (Medical/Non-medical) attended the awareness program.

6. AIIMS, Bhubaneswar

The sixth in the series was organized at AIIMS on 17th February, 2018. The dissemination program was attended by 642 participants from 34 institutes representing 25 EC members, 230 Faculty/Scientists and 271 Students.

7. Amrita Institute of Medical Sciences (AIMS), Kochi

This was the seventh in the series for the dissemination of the ICMR National Ethical Guidelines organized at Amrita Institute of Medical Sciences (AIMS), Kochi on 22nd February, 2018. 752 participants including 48 EC members, 176 Faculty/Scientists and 360 Students from 50 institutions attended the dissemination.

8. The Gauhati Medical College and Hospital, Guwahati

The eighth dissemination program was organized at Guwahati in Gauhati Medical College and Hospital on 08th March, 2018 and attended by 785 participants from 48 institutes. The stakeholders included 19 EC members, 135 Faculty/Scientists, 388 Students as well as representatives from Industry, NGO, Govt officials, etc.

9. Gadag Institute of Medical Sciences (GIMS), Gadag:

The first DHR-supported one day dissemination cum training program was organized on 7th March, 2019 at Gadag Institute of Medical Sciences (GIMS), Gadag. The program was attended by 259 participants from 40 institutes. Total 47 EC members, 97 faculty/scientist, 108 students and others attended the program

10. Kalinga Institute of Medical Sciences (KIMS), Bhubaneswar:

One day dissemination and a half day training program was organized at Kalinga Institute of Medical Sciences (KIMS), Bhubaneswar on 28th-29th June, 2019. The training program was attended by 245 participants from 61 institutes.

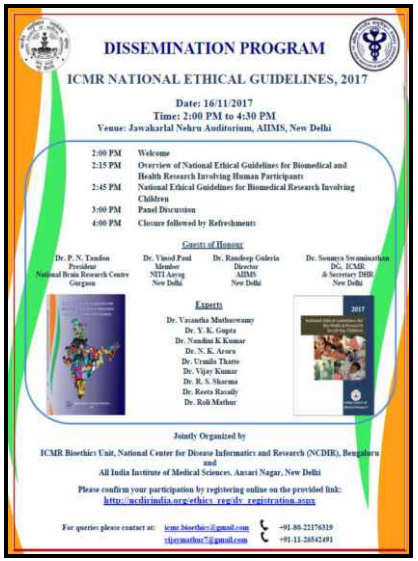
11. Jawaharlal Institute of Postgraduate Medical Education & Research (JIPMER), Puducherry:

Two-day workshop was organized on 16th-17th September, 2019 at Jawaharlal Institute of Postgraduate Medical Education & Research (JIPMER), Puducherry. The program was directed to train EC members and faculty from JIPMER and nearby medical colleges and research institutes. The training program was attended by 80 participants from 18 institutes.

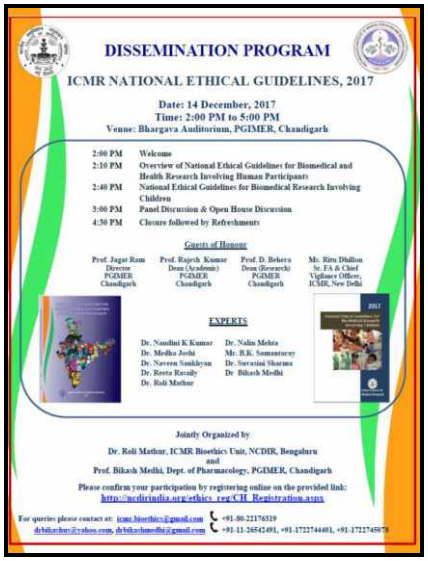
12. St. John's Medical College, Bangalore:

Half day dissemination and one day training program was organized at St. John's Medical College, Bangalore on 19th-20th September, 2019. The training program was attended by 45 EC members and faculty/scientists and dissemination program was attended by 162 participants. Total 207 participants attended by the program from 48 institutes.

KIMS, Bhubaneswar - Training

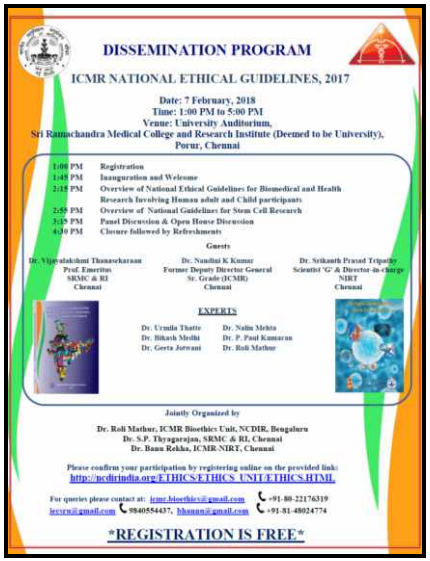


PGIMER, Chandigarh - Dissemination



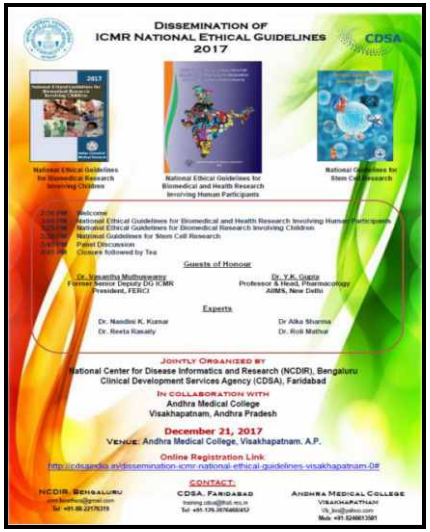
AIIMS, Bhubaneswar - Dissemination

SRMC, Chennai - Dissemination

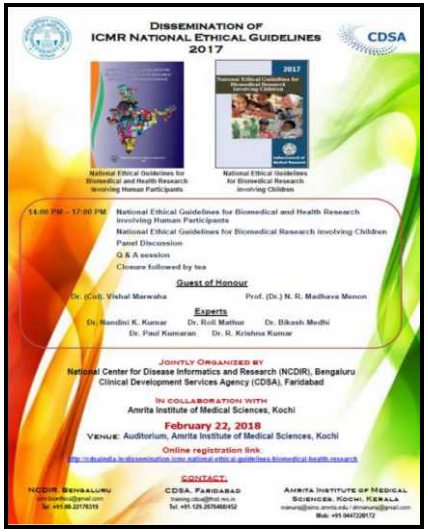


AMCMET, Ahmedabad - Dissemination

AMC, Visakhapatnam - Dissemination

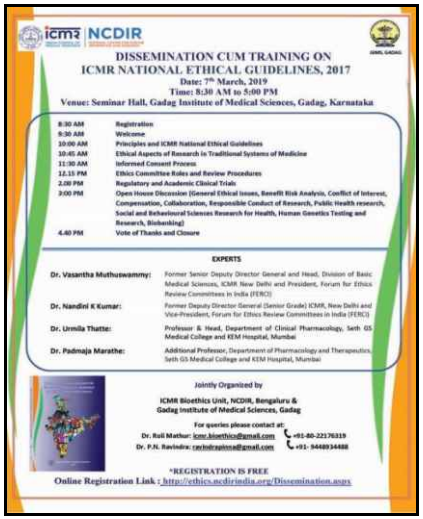


AIMS, Kochi - Dissemination

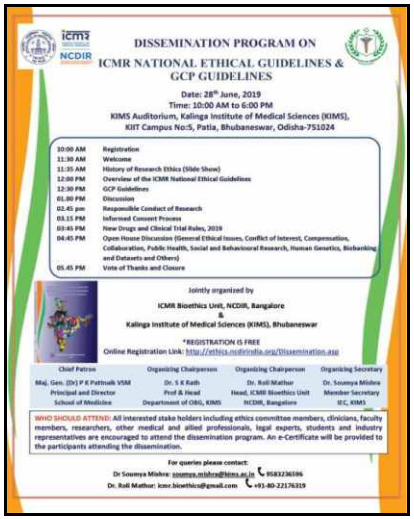


GMC, Guwahati - Dissemination

GIMS, Gadag – Dissemination cum Training



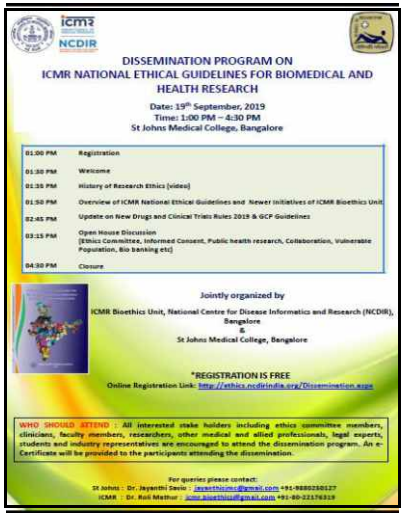
KIMS, Bhubaneswar - Dissemination



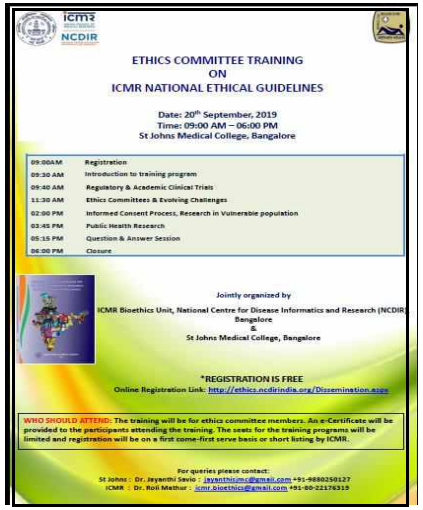
KIMS, Bhubaneswar - Training

JIPMER, Puducherry - Training

SJMC, Bangalore - Dissemination



SJMC, Bangalore - Training



Program:

1. **ICMR National Ethical Guidelines for Biomedical and Health Research Involving Human Participants:**

   The participants were updated about the addition of new sections in the ICMR National Ethical Guidelines for Biomedical and Health Research Involving Human Participants, 2017 such as Responsible Conduct of Research, Informed Consent Process, Vulnerability, Public Health Research, Social and Behavioural Sciences Research for Health, Biological materials, Biobanking and Datasets and Research during Humanitarian Emergencies and Disasters. Apart from these, many new issues have also been added up as subsections e.g. sexual minorities (LGBT), multicentric studies, research using datasets etc.

2. **ICMR National Ethical Guidelines for Biomedical Research Involving Children:**

   The overview of the 'National Ethical Guidelines for Biomedical Research Involving Children' was presented during the program. The participants were informed about the importance of including children in biomedical research and the guidelines have been specifically developed to safeguard children, who are potentially vulnerable and carry a greater risk of harm during research at all settings: hospital and community settings, children in emergency situations, school-based research, internet-based research. It was explained to the participant that the benefit of research carried out in adults cannot be applied to children, as the doses and duration of therapy, pharmacodynamics, adverse effects of drugs in children vary from adults.

3. **ICMR-DBT National Guidelines for Stem Cell Research:**

   The highlights of the ICMR-DBT National Guidelines for Stem Cell was also presented and the participants were updated about the various requirement for conducting research on Stem Cell such as approval from EC, Institutional Committee for Stem Cell Research (IC-SCR) and National Apex Committee for Stem Cell Research and Therapy (NAC-SCRT). The IC-SCR should be registered with NAC-SCRT. Clinical trials for stem cells to be undertaken at institutes with registered IC-SCR, EC and only at GMP and GLP certified facilities.

4. **Panel Discussions:**

   One of the major highlights of the dissemination programs were the Open House discussions. Open ended questions were addressed by the Panel and a time of about one and half hours allowed ample discussion. The session was greatly appreciated by the participants. The panelists were members of ICMR Ethics Advisory Committee, representatives from CDSCO or its expert committees, eminent experts, proficient in ethical and regulatory aspects of biomedical and health research and clinical trials in India. The questions raised by the audience mainly pertained to ethics committee functions and updates related to ethical and regulatory aspects of biomedical research as well as academic clinical trials and those clinical trials that are regulated by CDSCO. There were questions related to CTRI, EC accreditation, collaborative research, authorship issues, transfer of data and samples, change of PI, student research, etc. which the panel explained in detail. The participants benefitted to a great extent from the vast experience of the expert panel.

Limitations

As per feedback received, a number of participants indicated the need for full day program. It was also found that there was a need to improve the participation of ethics committee members as well as representatives from Government agencies and NGOs.

6. FUTURE STEPS

These outreach dissemination programs helped to create awareness and knowledge of relevant stakeholders about the updated requirements as specified in the National Ethical Guidelines which would eventually help to improve quality of biomedical and health research in India and ensure better protection is imparted to research participants to safeguard the dignity, rights, safety and well-being. There is a need for similar programs in non-metropolitan cities or rural/semi-urban institutions. Needful steps will be planned in this direction.

7. REFERENCES

1. ICMR National Ethical Guidelines for Biomedical and Health Research Involving Human Participants, 2017 (http://ethics.ncdirindia.org//asset/pdf/ICMR_National_Ethical_Guidelines.pdf)
2. National Ethical Guidelines for Biomedical and Health Research Involving Human Participants, 2017: A commentary. Indian Journal of Medical Ethics. 2018 Jul-Sep; 3(3):201-20
3. National ethical guidelines for biomedical & health research involving human participants, 2017: A commentary. Indian Journal of Medical Research. 2018 Mar 1; 148(3):279
4. ICMR National Ethical Guidelines for Biomedical Research Involving Children, 2017 (http://ethics.ncdirindia.org//asset/pdf/National_Ethical_Guidelines_for_BioMedical_Research_Involving_Children.pdf)
5. National Guidelines for Stem Cell Research. Indian Council of Medical Research and Department of Biotechnology (ICMR-BDT), 2017
6. ICMR Bioethics Unit - http://ethics.ncdirindia.org/Default.aspx

8. ANNEXURES

Annexure - A : Poster of ICMR National Ethical Guidelines for Biomedical and Health Research Involving Human Participants

NATIONAL ETHICAL GUIDELINES FOR BIOMEDICAL AND HEALTH RESEARCH INVOLVING HUMAN PARTICIPANTS, 2017

STATEMENT OF GENERAL PRINCIPLES

There are four basic principles namely; respect for persons (autonomy), beneficence, non-maleficence and justice and 12 general principles and are to be applicable to all biomedical, social and behavioural science research for health involving human participants, their biological material and data

GENERAL PRINCIPLES

Principle of essentiality.	Principle of professional competence.
Principle of voluntariness	Principle of maximization of benefit.
Principle of non-exploitation.	Principle of institutional arrangements.
Principle of social responsibility.	Principle of transparency and accountability.
Principle of ensuring privacy and confidentiality	Principle of totality of responsibility
Principle of risk minimization	Principle of environmental protection.

ETHICAL REVIEW PROCEDURES

- All types of biomedical and health research must be reviewed by an EC before it is conducted.
- EC should be multi-disciplinary, multi-sectoral, competent and independent in its functioning.
- EC is responsible for prior scientific and ethical review as well as monitoring.
- Institution is responsible for establishing an Ethics Committee (EC) and providing logistical support and protected time for the Member Secretary to run the EC functions.
- EC members have a defined role and responsibility. EC members should be trained in protection of human research participants, SOP and Good Clinical Practice (GCP) guidelines, and be conversant with relevant ethical guidelines and regulations.
- Larger institutions can have more than one EC while smaller institutions may utilize the services of other institutions under an MoU.
- The EC monitors progress of ongoing proposals, reviews SAEs, protocol deviations/violations, new information and final reports.
- ECs should be registered with the relevant authority and should make efforts to seek recognition or accreditation.

CLINICAL TRIALS OF DRUGS AND OTHER INTERVENTIONS

- Clinical trials must be conducted in accordance with the Indian GCP guidelines, Declaration of Helsinki, National Ethical Guidelines for Biomedical and Health Research Involving Human Participants (2017), amendments to the Drugs & Cosmetics Act (1940), and Rules (1945) and other applicable regulations and guidelines.
- ECs should register and follow the quorum requirements specified by CDSCO before reviewing clinical trials on 'new drugs' as per Schedule Y and its amendments.
- For investigator initiated clinical trials the investigator has the dual responsibility of being an investigator as well as the sponsor.
- For student conducting clinical trials as part of their academic thesis, the guide and the academic institution should take up the responsibilities of the sponsor.
- Ancillary care may be provided to clinical trial participants for non-study/trial related illnesses arising during the period of the trial.
- Therapeutic misconception is high in oncology trials; therefore, due care should be taken to address this issue.
- Any product using new technology should be GLP (Good Laboratory Practices), GMP (Good Manufacturing Practices) and GCP compliant, which should be duly approved by appropriate authorities.

BIOLOGICAL MATERIALS, BIOBANKING AND DATASETS

- Ethical issues such as ownership of samples or data, transfer of biospecimens, custodianship, secondary use, return of results, etc. are important.
- Samples/data may be anonymous (unidentified); anonymized (coded reversibly or irreversibly) or identifiable.
- The participant owns the biological sample and data collected. Informed consent should provide information about the commercial value of samples or data, if applicable, with clarity about benefit sharing.
- Material transfer agreement (MTA) should be executed if the biospecimens are likely to be shipped to collaborators within or outside the country.
- Privacy and confidentiality should be ensured when databases are maintained in electronic/digital formats which are linked by Internet, cloud computing or are associated with big data initiatives.

GENERAL ETHICAL ISSUES

Benefit–risk assessment	Informed consent process	Privacy and confidentiality
Distributive justice	Payment for participation	Compensation for research related harm
Ancillary care	Conflict of interest	Post-research access and benefit sharing
Community engagement	Selection of vulnerable and special groups as research participants	

- Categories of risk : - Less than minimal risk, Minimal risk, Minor increase over minimal risk or Low risk, More than minimal risk or High risk.
- Host institution is responsible to provide compensation/cover for insurance for research related injury or harm to be paid as decided by the EC through insurance, corpus funds, grants.
- Post-research access and benefit-sharing may be done with individuals, communities and populations, wherever applicable .

INFORMED CONSENT PROCESS

3 main Components–Information, Comprehension, Voluntariness.

Elements of an ICD	Additional elements (optional)
1. Statement that it is research.	1. Alternative procedures
2. Purpose and methodology	2. Insurance coverage
3. Benefits to participant/ community/ others	3. Possible stigmatizing condition.
4. Anticipated risks/ discomfort/inconvenience	4. Biological material and data, including : Period of storage, Sharing of data, Confidentiality, Right to prevent use of biological sample, Post-research plan/ benefit sharing , Publication plans.
5. Confidentiality of records	
6. Payment and treatment	
7. Freedom to participate/withdraw	

- Researchers should only use the EC approved version of the consent form and its translation in local languages.
- In case of research involving children, in addition to parental consent, verbal (7-12 years) or simplified written (>12 – 18 years) assent should also be taken from the participant.
- The use of Electronic/Online consent especially for conducting research involving sensitive data.
- Researchers can apply to the EC for a waiver of consent if the research involves less than minimal risk to participants.

PUBLIC HEALTH RESEARCH & SOCIAL AND BEHAVIOURAL SCIENCES RESEARCH FOR HEALTH

- Benefits and risks in public health research may not be limited to an individual, but may influence communities, populations and the environment.
- Social and behavioural studies must ensure social equity and inter sectionality. Ethical relativism applies to moral diversity among different cultures and societies.
- Based on specific research, appropriate consent processes may be considered by the EC, such as verbal/oral consent; broad consent; group consent; waiver of consent and reconsent.
- Engagement with all stakeholders (researchers, public health providers/professionals, sponsors, Govt. agencies, participants, ECs, institutions, NGOs and others).
- ECs should ensure measures has taken for data security, confidentiality of information, disclosure permissions and stated appropriate use of the accessed data.
- The researchers, research team and EC must recognize the cultural context and associated harm related to dignity as well as social and informational harm.
- Support systems such as counselling centres, rehabilitation centres, police protection, etc. should be in place for sensitive studies.

HIGHLIGHTS

- The principles of social responsibility and environmental protection have been added in order to stress the need for protecting social and cultural harmony and conserving our limited resources.
- Risk categorisation added to help ethics committees (EC) conduct a more objective benefit-risk assessment.
- Newer sections on responsible conduct of research (including publication ethics), public health research, socio-behavioural research, and research during humanitarian disasters and emergencies added.
- For the first time in India, the guidelines have proposed that a common EC may be identified from the participating sites to act as the main designated EC for review of multicentric research.
- Guidelines suggested that any institutions must make prior provisions to create a corpus fund, insurance coverage, grants for payment of compensation.

The guidelines would help in upholding the principles of bioethics and thereby imparting protection to patients as well as volunteers who become part of research.

RESPONSIBLE CONDUCT OF RESEARCH

- Values of research - honesty, accuracy, efficiency, fairness, objectivity, reliability, accountability, transparency, personal integrity, and knowledge of current best practices.
- Establish specific issues while planning and conducting research:
  - Conflict of Interest policies,
  - data sharing & acquisition, management, ownership issues etc.
  - policies for handling Research misconduct.
- Completed research, irrespective of results, must be published in accordance with the guidelines of the International Committee of Medical Journal Editors (ICMJE).
- For multicentric collaborative research national/International there is a need for MoU and MTA and communications between EC's. Common review by Designated EC in order to save time, effort and improve quality of the review process in multicentric research.
- Clinical studies on human participants should be registered prospectively with the Clinical Trial Registry - India (CTRI). This is mandatory for regulatory trials.

VULNERABILITY

- Vulnerable persons are relatively or absolutely incapable of protecting their interest.
- Vulnerable populations have an equal right to be included in research so that benefits accruing from the research apply to them as well.
- Researchers must justify the inclusion/exclusion and take additional precaution to avoid exploitation.
- Research on sensitive issues such as mental health, sexual practices/preferences, HIV/AIDS, substance abuse, etc. may present special risks to research participants.
- Full committee should do initial and continuing review of proposals involving vulnerable populations.
- EC may include a representative of the group as a special invitee/member to participate in the meeting of the EC.
- Whenever possible, ancillary care may be provided .
- Research involving cognitively impaired individuals or those with mental illness must be done carefully, especially if there is risk to themselves, to others or suicidal ideation.
- The EC should carry out the benefit–risk analysis and examine risk minimization strategies.

HUMAN GENETICS TESTING AND RESEARCH

- Due to an overlap between genetic research and services, therapeutic misconception is common and ethical, legal and social issues (ELSI) require careful consideration.
- Genetic test results have familial/societal implications, therefore, maintaining confidentiality and providing pre- and post-test non-directive counselling by qualified persons is important.
- Genetic screening should be purposive, with established provisions for disease management, treatment and counselling.
- Quality standards of the laboratory to avoid misinterpretation of genetic results or misdiagnosis to avoid psychological harm, and unnecessary or inappropriate intervention.
- Information about a patient's disease and investigations may not be shared to avoid misuse of genetic technology.
- EC reviewing genetic research should have necessary expertise to understand the ethical implications and provide safeguards.
- Publication of pictures, pedigrees or other identifying information about individuals/ families requires fresh or re-consent.
- Confidentiality must be maintained while using new technologies like chromosomal microarray (CMA), whole exome sequencing, whole genome sequencing, etc.

RESEARCH DURING HUMANITARIAN EMERGENCIES AND DISASTERS

- Pre-emptive research preparation can be done much in advance of a future humanitarian emergency by researchers and sponsors. Meticulous documentation and archiving are required to enable future application in similar situations.
- Efforts should be made to protect the identifying information about individuals and communities to prevent stigmatization, ostracization and exploitation by the print and visual media.
- Research during humanitarian emergencies and disasters can be reviewed through an expedited review/scheduled or unscheduled meetings and decided on a case-to-case basis.
- In case of an outbreak of infectious diseases, monitored emergency use of unregistered and experimental interventions (MEURI) may be approved with close monitoring.
- EC could review proposals prior to the occurrence of the humanitarian emergencies, disasters and determine who could be an acceptable LAR.
- If an expedited review is done, full ethical review should follow along with careful monitoring by the EC.

CONTACT DETAILS: ICMR- Bioethics unit National Centre for Disease Informatics and Research II Floor of Nirmal Bhawan, ICMR Complex, Poojanhalli Road, Off NH-7, Adjacent to Trumpet Flyover of BIAL Kannamangala, Bangalore, 562110
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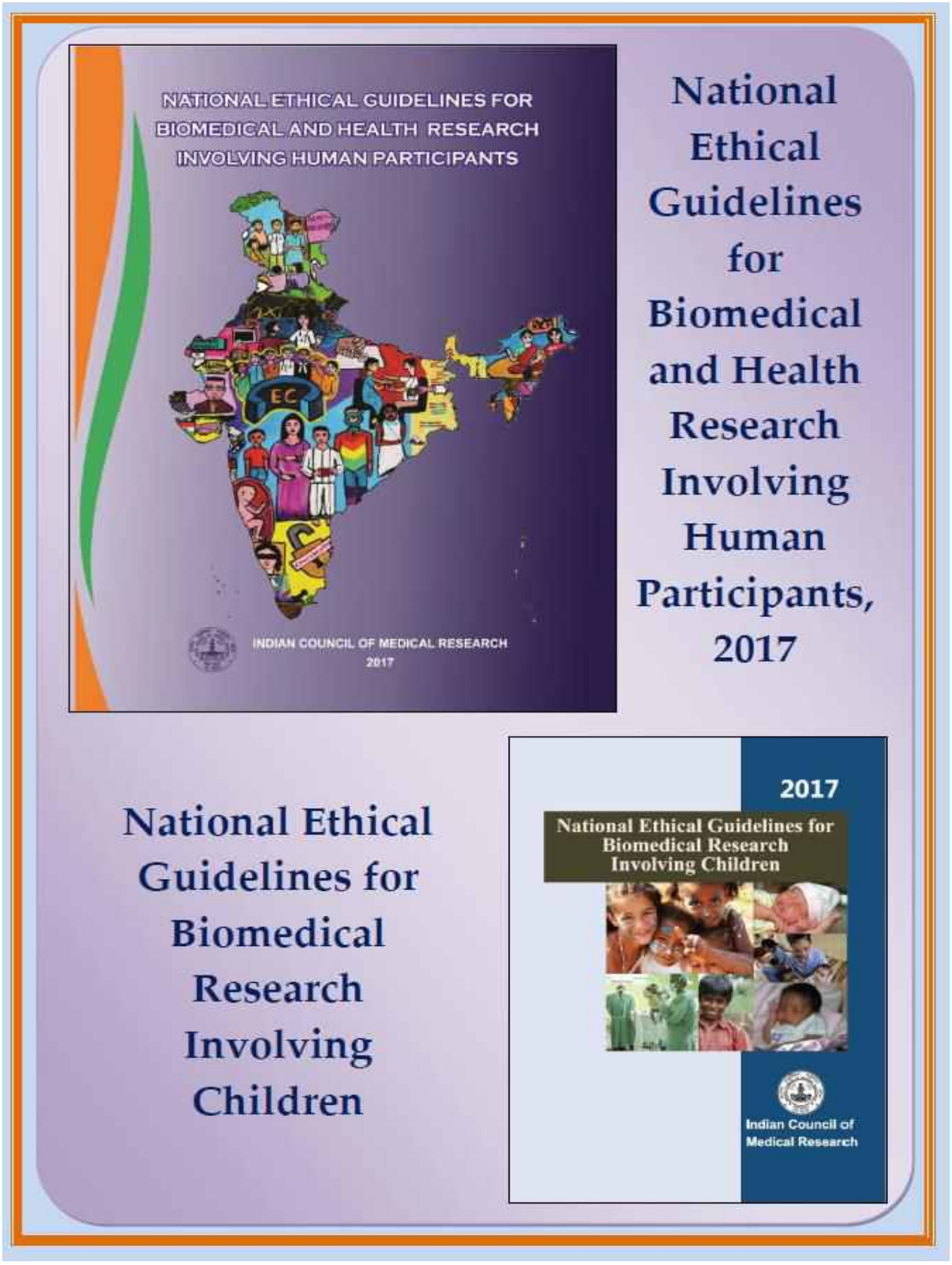
Annexure - b): Pamphlet with Salient features of ICMR National Ethical Guidelines for Biomedical and Health Research Involving Human Participants & National Ethical Guidelines for Biomedical Research Involving Children



National Ethical Guidelines for Biomedical and Health Research

Salient features

- ICMR has prepared two national Guidelines 'National Ethical Guidelines for Biomedical and Health Research involving Human Participants, 2017' and 'National Ethical Guidelines for Biomedical Research Involving Children' to guide biomedical and health research and to ensure protection of the common man in the conduct of biomedical and health research.

- The guidelines were released by Shri JP Nadda, Hon Minister of Health and Family Welfare and Smt Anupriya Patel, Hon'Minister of State for Health & Family Welfare on 12th Oct at ICMR headquarters, New Delhi.

- In order to create awareness amongst all the stakeholders such as clinicians, researchers, ethics committee member, students, nurses as well as faculty involved in biomedical research, a series of dissemination programs are being planned.

- ICMR being the apex body for biomedical and health research not only promotes and funds research but also would like to ensure adequate protection of human being who participate in this research to make sure there is no exploitation and the rights, welfare and safety of individuals is protected.

- Ethics is not part of regular teaching curriculum in most of the medical colleges or university courses and therefore the medical as well as non medical students as well as researchers are not aware of the requirements. ICMR has taken a lead in this area and prepared guidelines for the country right from 1980 and revised them from time to time. With the evolving ethical concerns, there was a felt need to prepare a detailed guidance and National Ethical Guidelines for Biomedical and Health research to be conducted both on general populations and also on guidelines specific to children were prepared.

- The guidelines are applicable to all types of biomedical and health research conducted across the country whether it is clinical research, basic sciences, epidemiological, socio-behavioural, public health research or that which involves data or samples. The guidelines would really help in upholding the principles of bioethics and thereby imparting protection to patients as well as volunteers who become part of research.

- The guidelines have been updated and harmonised with national and international requirements and is a landmark document for being comprehensive and user friendly while covering a range of topics.

- The preparation of guidelines was a participatory process involving large number of stakeholders from various backgrounds. A 6 member Core Advisory Committee prepared an outline and 48 members in 12 Sub committees prepared the initial Draft of the 12 sections of the Guidelines. Additional suggestions were sought from subject experts and the guidelines were harmonized with national International requirements and thoroughly reviewed by the Core Group. They were posted on ICMR website for 10 weeks for public Consultation and >9000 comments were received from stakeholders across the country and internationally too. Thereafter face to face Regional Consultation National Consultation meetings with about 75 stakeholders each was held in Bangalore and New Delhi to consult not only with researchers, scientists, clinicians, ethics committee members but to also know the perspectives of the sponsors, lawyers, social scientists, patient representative groups, non-governmental organizations, regulators, representatives from relevant Ministries and Departments.

- Researchers as well as ethics committees (ECs) play an important role in the conduct of research and its prior review. The guidelines have suggested that institutions should set up ethics committees and provide dedicated support to run the ethics committee as so far in most medical colleges and research institutes there is no allocated space, infrastructure or manpower for ethics committee office.

- For the first time, the guidelines have addressed concerns in subject areas where there is scanty guidance available such as responsible conduct of research, public health research, socio-behavioral research, conducting research during humanitarian emergencies or disasters, dealing with vulnerable populations or conducting collaborative research, stored samples, biological materials, biobanking and datasets.
- There are societal concerns that humans are used as guinea pigs in research. The sections on informed consent and ethics review process have been elaborated and ECs and researchers have been guided about how to safeguard the interests, rights, safety, well being, privacy and confidentiality of the participants/samples/data. The guidelines explain the processes of benefit risk assessment, protecting privacy and confidentiality, prevention against stigmatization or discrimination, community engagement and benefit sharing with the research participants or communities or population. Informed consent process section elaborates the various ways of ensuring better understanding and voluntariness of participants.
- The guidelines provide detailed guidance on collaborative research as well as International collaboration and describe the requirements of ethical approval, ownership of samples and data, its analysis, publication as well as dissemination. It also describes the need to communicate the findings of the research with the providers (participants/communities).
- For the first time, the guidelines have discussed about common ethical review of multicentric research by a designated main Ethics committee instead of review by separate ethics committee for studies which involve low risk. This will not only reduce duplication of efforts and save time but also create networking and communication channels between ethics committees to conduct more meaningful research.
- Payment of compensation in case of injury is a difficulty area and for the first time it has been suggested that any institution that engages in biomedical and health research must make prior provisions such as to create a corpus fund in the institution, or to seek insurance coverage, or to seek grants from various agencies who sponsor research.

- The guidelines discuss procedures for declaration and management of conflicts of interests in research that exists at the level of researchers as well as ethics committee members.
- The ethical issues related to research involving new technologies such as genetic studies, CRISPR technology etc. The specific guidance has been provided to address the various ethical issues related to Public health research, Social and behavioural sciences research as there is lack of awareness about the requirements of research which pertains to public health. Also it discusses research using traditional medicine.
- Vulnerability has been clearly defined since there was no clarity on the subject. The additional safeguards that are required and also the obligations of the researchers, ethics committee members and sponsors have been explained.
- Vulnerable populations such as economically and socially disadvantaged individuals, orphans, abandoned individuals, children, women in special situations, individuals with neurological or mental disabilities, sexual minorities (LGBT), individuals/communities in humanitarian emergencies and disaster, etc. are incapable of protecting their own rights and interest. The revised guidelines give specific directions and guidance to researchers while planning and conducting research on such special populations with utmost ethical standards.
- The 'National Ethical Guidelines for Biomedical Research Involving Children' highlights the importance of including children in biomedical research. Benefit of research carried out in adults cannot be applied to children, as the doses and duration of therapy, pharmacodynamics, adverse effects of drugs in children vary from adults.
- The guidelines have been specifically developed to safeguard children, who are potentially vulnerable and carry a greater risk of harm during research at all settings: hospital and community settings, children in emergency situations, school based research, internet based research.
- These guidelines were prepared following extensive literature review and expert consensus to cover important ethical and legal issues which will be of immense help to researchers and ethics committees reviewing and monitoring research.

ICMR –WHO Regional Consultation at NCDIR, Bangalore on 4th October, 2016

ICMR–WHO National Consultation at ICMR Headquarters, New Delhi on 14th December, 2016

Release of the National Ethical Guidelines for Biomedical and health Research Involving Human participants, 2017 at ICMR Headquarters, New Delhi on 12 October 2017

Release of the National Ethical Guidelines for Biomedical research involving Children at ICMR Headquarters, New Delhi on 12 October 2017

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Website:- http://www.ncdirindia.org/index.aspx

Guidelines can be accessed from:

http:// www.icmr.nic.in/sites/default/files/guidelines/ICMR_Ethical_Guidelines_2017.pdf

and

http://ethics.ncdirindia.org//asset/pdf/ICMR_Ethical_Guidelines_for_biomedical_and_health_research_involving_human_participants_2017.pdf

Impacting NCD Public Health Actions and Policies
Collaborate Innovate Inspire

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