



# DISSEMINATION PROGRAM

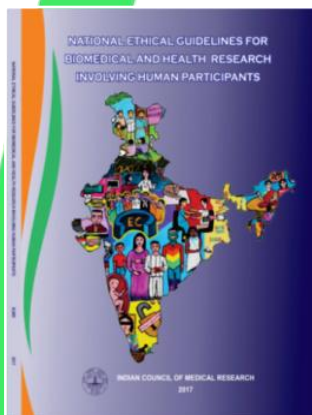
## ICMR NATIONAL ETHICAL GUIDELINES, 2017

Date: 17 February, 2018

Time: 1:30 PM to 5:00 PM

Venue: Auditorium, AIIMS Bhubaneswar

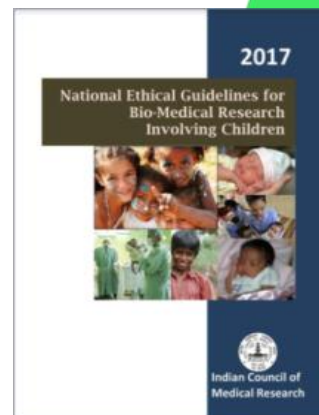
- |              |   |
|--------------|---|
| 1:30 PM-2 PM | Registration  |
| 2:00 PM      | Inauguration and Welcome  |
| 2:15 PM      | Overview of National Ethical Guidelines for Biomedical and Health Research Involving Human Participants |
| 2:45 PM      | Overview of National Ethical Guidelines for Biomedical Research Involving Children                      |
| 3:00 PM      | Panel Discussion & Open House Discussion  |
| 4:30 PM      | Closure followed by Refreshments  |



### EXPERTS

Dr. Nilima A. Kshirsagar  
Dr. Gitanjali Batmanabane  
Dr. Sanghamitra Pati  
Dr. Nalin Mehta  
Dr. Reeta Rasaily

Dr. Nandini K Kumar  
Dr. N. K. Arora  
Dr. Urmila Thatte  
Dr. Bikash Medhi  
Dr. Roli Mathur



Jointly Organized by

Dr. Roli Mathur, ICMR Bioethics Unit, NCDIR, Bengaluru  
&  
All India Institute of Medical Sciences, Bhubaneswar

Please confirm your participation by registering online on the provided link:  
[http://ncdirindia.org/ETHICS/ETHICS\\_UNIT/ETHICS.HTML](http://ncdirindia.org/ETHICS/ETHICS_UNIT/ETHICS.HTML)

For queries please contact at: [icmr.bioethics@gmail.com](mailto:icmr.bioethics@gmail.com)

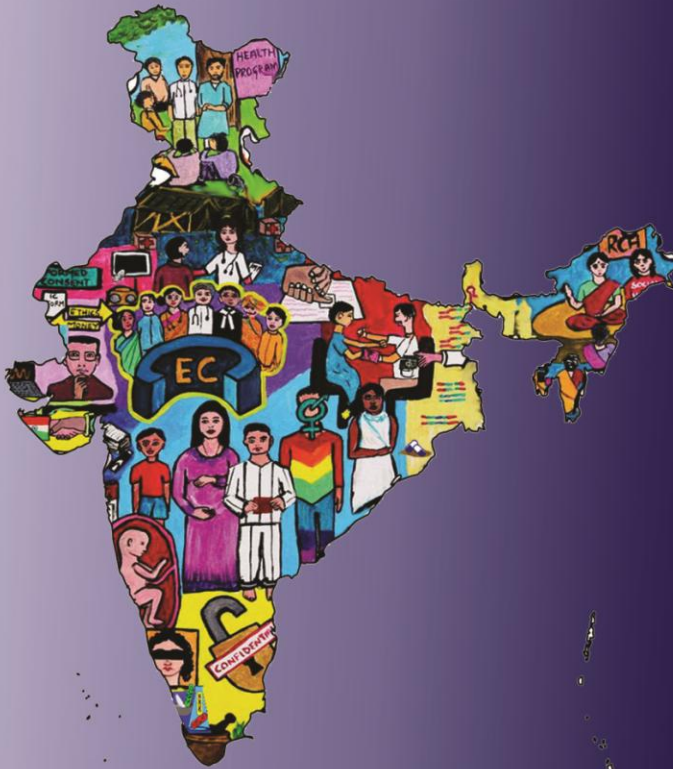
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**\*REGISTRATION IS FREE\***

NATIONAL ETHICAL GUIDELINES FOR  
BIOMEDICAL AND HEALTH RESEARCH  
INVOLVING HUMAN PARTICIPANTS



INDIAN COUNCIL OF MEDICAL RESEARCH  
2017

**National  
Ethical  
Guidelines  
for  
Biomedical  
and Health  
Research  
Involving  
Human  
Participants,  
2017**

**National Ethical  
Guidelines for  
Biomedical  
Research  
Involving  
Children**

2017

**National Ethical Guidelines for  
Biomedical Research  
Involving Children**



Indian Council of  
Medical Research



सत्यमेव जयते

**डा. सौम्या स्वामीनाथन**

एमडी, एफएएससी, एफएनएससी, एफएएएस

सचिव, भारत सरकार

स्वास्थ्य अनुसंधान विभाग

स्वास्थ्य एवं परिवार कल्याण मंत्रालय

एवं

महानिदेशक, आई सी एम आर

**Dr. Soumya Swaminathan**

MD, FASc, FNASc, FAMS

**Secretary to the Government of India**

Department of Health Research

Ministry of Health & Family Welfare

&

**Director-General, ICMR**



**भारतीय आयुर्विज्ञान अनुसंधान परिषद**

स्वास्थ्य अनुसंधान विभाग

स्वास्थ्य एवं परिवार कल्याण मंत्रालय

वी. रामलिंगस्वामी भवन, अंसारी नगर

नई दिल्ली-110 029 (भारत)

**Indian Council of Medical Research**

Department of Health Research

Ministry of Health & Family Welfare

V. Ramalingaswami Bhawan, Ansari Nagar

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## FOREWORD

I am very pleased that the ICMR ethical guidelines for research have been revised which were last brought out in 2006. ICMR has always been leading in developing ethical standards for human research in the country. These guidelines are well recognized in India and a number of other countries also.

Changes in biomedical health research and its environment have been very rapid in recent times. In India with its diverse population, it is very important to be sensitive to the needs and requirements for advances in medicine, while providing adequate protection to the vulnerable population. Medical research is the need of the hour and therefore it is important not only be responsive to emerging issues but to also build greater trust towards research. ICMR ethical guidelines have been developed after long and careful deliberations with experts and stakeholders, from various disciplines and constituencies 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 existing 2006 guideline but also address newer concerns, in accordance with the socio-cultural milieu of our country. For the first time, the guidelines have addressed concerns in subject areas where there is scanty guidance available such as public health research, socio behavioural research, conducting research during disasters or emergencies, dealing with vulnerable populations or conducting collaborative research. It is thus important that every stakeholder, whether a researcher or a member of an ethics committee, or a sponsor, is aware of the provisions made in the revised ethical guidelines, which would help improve the conduct of biomedical research in India.

I look forward to this document being widely referred to and used towards achieving high quality of conduct of ethical health research in the country.

  
(Soumya Swaminathan)

# 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.

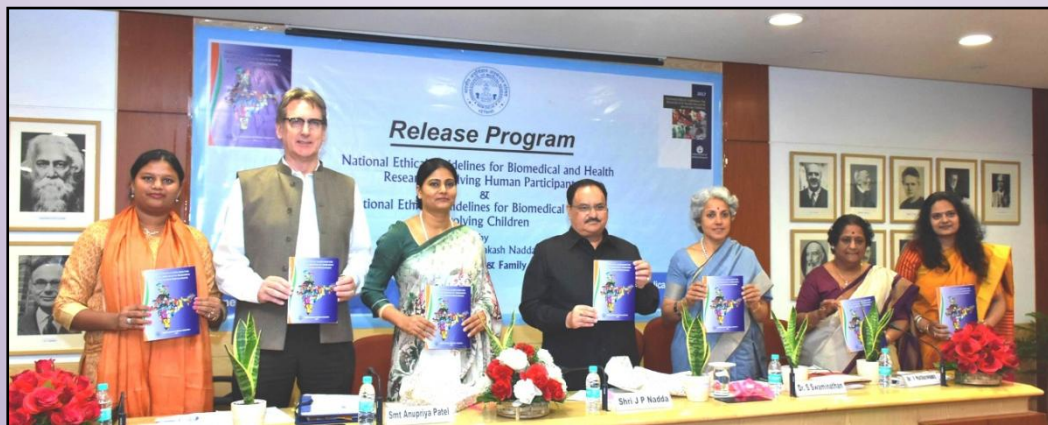
**ICMR –WHO Regional Consultation at NCDIR, Bangalore on 4th October, 2016**



**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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**Guidelines can be accessed from:**

[http://www.icmr.nic.in/guidelines/ICMR\\_Ethical\\_Guidelines\\_2017.pdf](http://www.icmr.nic.in/guidelines/ICMR_Ethical_Guidelines_2017.pdf)

and

[http://www.icmr.nic.in/guidelines/National\\_Ethical\\_Guidelines\\_for\\_BioMedical\\_Research\\_Involving\\_Children.pdf](http://www.icmr.nic.in/guidelines/National_Ethical_Guidelines_for_BioMedical_Research_Involving_Children.pdf)