ICMR-WHO

Consultation on "National Ethical Guidelines for Biomedical and Health Research involving Human Participants, 2016-2017"- A Report

ICMR Bioethics Unit
NCDIR, Bangalore

ICMR-WHO Consultation Meeting

"National Ethical Guidelines for Biomedical and Health Research involving Human Participants"

National Centre for Disease Informatics and Research (NCDIR), ICMR

Bangalore

Contents

Foreword

Regional and National consultation meetings were organised by ICMR in collaboration with WHO Country Office to gather inputs and comments from various stakeholders before finalising the draft "Ethical guidelines for biomedical and health research involving human participants". The core group and subcommittee members developed the zero draft and Guidelines.

ICMR brought out the first guidelines in 1980 and subsequently revised in 2000 and updated in 2006. These are looked upon by stakeholders all over the country, e.g. researchers including UG and PG students, faculty members, Institutional ethics committees and regulators as gold standard. Since the last 10 years so many developments and new concerns have evolved over the ethical dilemmas faced by the scientific and ethical committees, that it had become necessary to revisit the 2006 guidelines and develop a state of art guidelines including all contemporary issues. The new draft developed in this regard has many new sections added up and many changes incorporated in the existing sections and finally was posted for Public consultation. The response was very encouraging. In addition to appreciation huge amount of comments were received from not only biomedical researchers, but from NGOs, international agencies, industry related organisations etc. ICMR guidelines are looked upon by many developing countries as a guidance document.

The comments received during these consultation meetings will offer definite inputs to improve and finalise the guidelines which will be feasible, implementable and acceptable to all stakeholders involved in clinical research. The support given to the drafting committee by ICMR and WHO to complete the work within the stipulated time needs appreciation.

Date
Coimbatore

Dr Vasantha Muthuswamy
Chairperson, Advisory Committee

Message from Director

I am pleased to present the consolidated report of the ICMR–WHO Consultation Meetings. It gives an insight to the proceedings of the Regional Consultation meeting held on 4th of October 2016 at National Center for Disease Informatics and Research (NCDIR), Bengaluru and National Consultation meeting held on 14th of December, 2016 at ICMR Headquarters, New Delhi. I would like to offer my sincere thanks to Dr Soumya Swaminathan, Secretary DHR and DG ICMR, Dr. Henk Bekedam, WHO representative, India and Dr. Madhur Gupta, Technical Officer, WHO Country Office for India, all the advisory group members, subcommittee members and many others for both scientific as well as administrative support towards the workshops for finalization of the draft ethical guidelines. Ethics is about views and opinions and it is necessary to find the appropriate path to consider conceptualized factors and societal perspectives to refine the draft guidelines. Experts from different disciplines like physicians, social scientists, legal experts, industry, civil society, etc. as well as senior scientists of national and international stature participated in the consultation meetings. The Bioethics discipline has been transferred from the ICMR Hqtrs, New Delhi to NCDIR, Bangalore and an ICMR Bioethics Unit has been set up at NCDIR. These two consultations were one of the first initiatives and the Unit carried out successfully in collaboration and partnership. This enthusiasm will facilitate further work in the area of Bioethics as is needed by the country.

Bangalore
24.3.2017

Dr Prashant Mathur
Director, NCDIR

Acknowledgement

ICMR is revising the Ethical Guidelines for biomedical and health research and taking several initiatives to make the process participatory so as to invite and receive feedback from variety of stakeholders involved in biomedical and health research. I am thankful to WHO-Country Office for India for agreeing to collaborate with ICMR for holding two consultation meetings in October, 2016 at Bengaluru and December, 2016 at New Delhi. A very large number of experts from various backgrounds and expertise participated in both the consultation meetings and provided very valuable feedback that was useful in the process of updation of Ethical Guidelines. I thank all who actively contributed to this exercise and shared their opinions.

I take this opportunity to thank Dr. Soumya Swaminathan, DG ICMR, for her interest, encouragement and immense support. My special thanks to all the members of the advisory group, Dr Vasantha Muthuswamy for chairing the sessions and Dr S D Seth, Co-Chair, Dr N K Arora, Dr Nandini K Kumar, Dr Urmila Thatte, Dr Vijay Kumar for their intellectual inputs and critical reviews. I also express my gratitude to Dr. Henk Bekedam, WHO representative, India and Dr. Madhur Gupta, Technical Officer, WHO Country Office for India for the technical collaboration with ICMR in organizing the consultation meetings. I thank scientific and administrative staff at NCDIR Bangalore for their involvement and support. Dr Rajib, Dr Kalyani and Ms Shabeen have worked day and night to make the two events a success.

I hope that the inputs received during these consultation meetings will immensely benefit us in the process of finalization of the draft ethical guidelines.

Bangalore
24.3.2017

Dr Roli Mathur
Scientist E & Head
ICMR Bioethics Unit

Abbreviations

CDSCO	Central Drugs Standard Control Organization
CECHR	Central Ethics Committee on Human Research
COI	Conflict of Interest
CTRI	Clinical Trials Registry of India
DCGI	Drugs Controller General of India
EC	Ethics Committee
GCP	Good Clinical Practice
GOI	Government of India
HMSC	Health Ministry Screening Committee
IC	Informed Consent
ICD	Informed Consent Document
ICF	Informed Consent Form
ICMR	Indian Council of Medical Research
LAR	Legally Acceptable/ Authorized Representative
MoU	Memorandum of Understanding
NCDIR	National Centre for Disease Informatics and Research
PIS	Patient Information Sheet/ Document
ROHC	Regional Occupational Health Centre
SAE	Serious Adverse Event
SOP	Standard Operating Procedure
WHO	World Health Organization

Executive Summary

In India, Indian Council of Medical Research (ICMR) has been on the forefront to set the standards for defining the ethical requirement for biomedical and health research. The ICMR ethical guidelines have provided the right direction to the researchers for conducting biomedical and health research in the country.

After a series of meetings and deliberations, the draft of the **National Ethical Guidelines for Biomedical and Health Research involving Human Participants** has been finalized by ICMR. The draft guideline was made ready for public consultation and posted on ICMR website to invite comments from all interested stakeholders.

In order to improve the consultation process and receive feedback from experts, ICMR in collaboration with the World Health Organization-Country Office for India had jointly organized the Regional and National consultation meetings on 4th October, 2016 at National Centre for Disease Informatics and Research (NCDIR), Bangalore and on 14th December, 2016 at ICMR Headquarters, New Delhi. Both the meetings were very useful in obtaining valuable feedback about revised guidelines from experts.

Regional Consultation:

The consultation meeting was aimed at inviting comments and feedbacks from various stakeholders from all parts of the country including East, West, South and North regarding the draft ethical guidelines. This meeting was attended by 94 participants from different areas, including social scientist, legal experts, representatives from the pharma industry, academic institution in public and private, Non Governmental Organisations etc. and many others from across the country as well as in house scientists and staff of NCDIR, Bangalore. The consultation received a very good feedback from participants.

With a warm welcome Dr. Prashant Mathur, Director, NCDIR, Bangalore, briefly introduced the objectives of the consultation meeting for the National Ethical Guidelines for Biomedical and Health Research involving Human Participants. Dr. Vasantha Muthuswamy, Chairperson, advisory group committee, gave a brief account of the process of revision of ICMR ethical guidelines from 1980 to 2016. Dr. Madhur Gupta, Technical Officer, WHO Country Office for India said that WHO has been privileged to be closely working with ICMR from many years in supporting the agenda of ethics and the current draft guidelines have extensively referred to the emerging ethical issues in the biomedical and health research incorporating all major evidences. Video message of Dr. Soumya Swaminathan, Secretary, DHR & DG ICMR, was played for the audience. Dr. Roli Mathur, Scientist E and Head, ICMR Bioethics Unit, NCDIR, Bangalore, thanked the guests for gracing the occasion and introduced the process of consultation meeting through panel discussions for all the sections of the draft guidelines.

To facilitate the focussed discussions on various ethical issues, the 14 sections of the draft guidelines were divided in 6 panels. All the panelists, moderators, dignitaries and senior experts participated in the discussion

and suggested some recommendations/ changes for the draft ethical guidelines. During the panel discussion, feedbacks from various stakeholders were collected for further incorporation and discussion in the next advisory group meeting to finalize the draft National Ethical Guidelines for Biomedical and Health Research involving Human Participants.

National Consultation:

National Consultation Meeting was held on 14th December, 2016 at ICMR Headquarters, New Delhi. The meeting was aimed at finalizing the draft with the approval from DG, ICMR, CECHR members and other invited experts. Meeting was attended by 68 expert participants from various parts of the country. The invited experts discussed the major ethical challenges and significant role of ICMR Ethical Guidelines in Biomedical Research involving Human Participants.

With the warm welcome to all the participants, Dr. Roli Mathur, Scientist E & Head, ICMR Bioethics Unit, NCDIR, Bangalore, discussed the journey of the draft ethical guidelines from the zero draft to revised draft ethical guidelines. Dr. S. D. Seth, Co-Chairperson, advisory group committee gave a brief account of the revision of ICMR ethical guidelines. The advisory group members - Dr. N. K. Arora, Dr. Nandini K Kumar, Dr. Urmila Thatte and Dr. Vijay Kumar discussed on the various sections and the changes made under each section. Dr. Henk Bekedam, WHO Representative, Country Office for India said that WHO has been privileged to be closely working with ICMR and discussed the importance of ethics in India and the major role played by the advisory group from the zero draft to the revised ethical guidelines. He also discussed about the online courses for ethics which needs to be implemented from ICMR. Dr. Soumya Swaminathan, Secretary, DHR & DG ICMR, welcomed the guests and thanked them for sparing their valuable time. She congratulated all the advisory group members for their efforts and also thanked WHO for their support to organize the consultation meetings for finalizing the draft guidelines. She discussed the efforts of ICMR and DHR in improving the quality of research and informed about the initiative to introduce the online course on ethics. Dr. Roli Mathur thanked the invited guests for gracing the occasion.

To facilitate the focussed discussions on various ethical issues, the 13 sections of the draft guidelines were divided in 6 panels. All the dignitaries and senior experts participated in the panel discussion and suggested some recommendations/ changes for the revision of ethical guidelines. During the panel discussions, feedbacks from various stakeholders was received and recorded for incorporation in the revised draft of guidelines.

ICMR –WHO Regional Consultation

On

"National Ethical Guidelines for Biomedical and Health Research involving Human Participants"

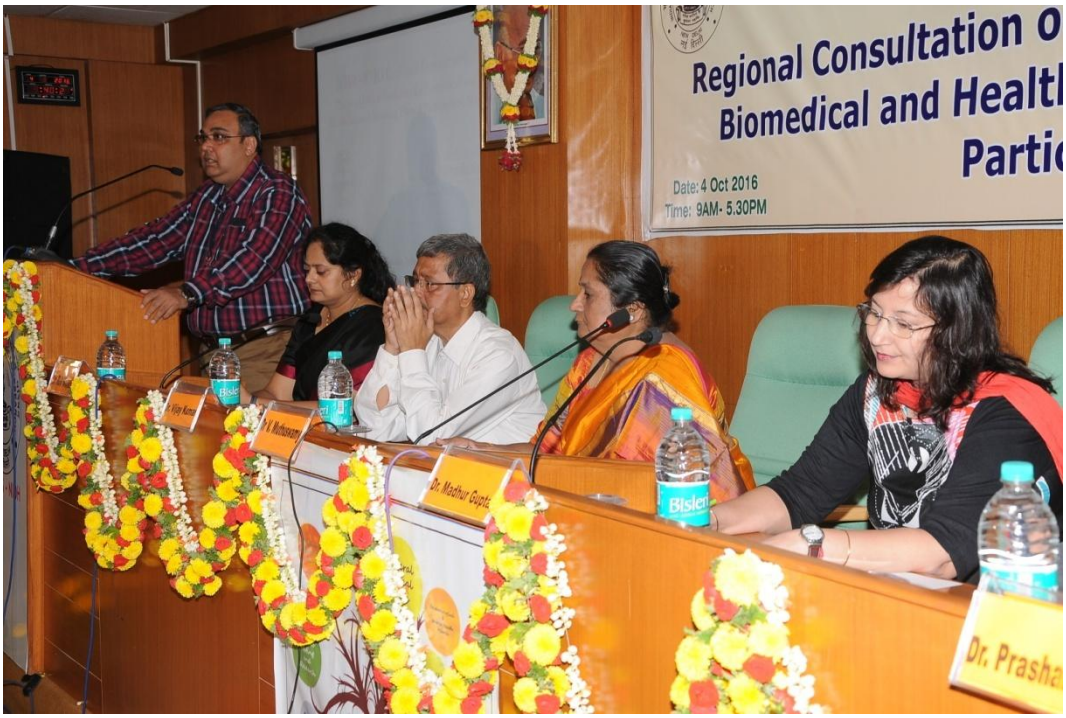
At

National Centre for Disease Informatics and Research

4th October, 2016, Bangalore

Proceedings of the Regional Consultation Meeting

Welcome and Opening Remarks



Welcome and Opening Remarks

Remarks by Director, NCDIR

Dr. Prashant Mathur, Director, NCDIR (ICMR), Bangalore welcomed all the guests to the ICMR–WHO Regional Consultation on "National Ethical Guidelines for Biomedical and Health Research involving Human Participants". He emphasized the need for revision of "Ethical Guidelines for Biomedical Research involving Human Participants" in the current scenario. He thanked WHO Country Office India for their collaboration and jointly organizing this meeting. He mentioned that ethics is about views and opinions and it is necessary to find appropriate path to consider conceptualized factors and societal perspectives which have been considered while refining the draft guidelines. He thanked the experts from different quarters of life like social scientists, legal experts, those from pharma industries and many other very senior experts for their valuable feedback. He said that their feedback would be enriching to the process of revision of ethical guidelines.

Remarks by Chairperson, Advisory Group

Dr. Vasantha Muthuswamy, Chairperson, advisory group, shared the procedure adopted for revision of ethical guidelines. She informed how the core group and subcommittee members drafted the zero draft, revised it many times and finalized the draft national ethical guidelines. She thanked all the members of advisory group and subcommittees. She discussed about the comments and appreciation received from all quarters, not only from biomedical researchers, but also from NGOs, Govt institutions, international agencies like NIH, OHRP and many others. ICMR guidelines are looked upon by many developing countries and the revised documents would be useful for researchers as well as for EC members.

Remarks by Technical Officer, WHO India

Dr. Madhur Gupta, WHO representative, thanked Dr. Vasantha Muthuswamy for chairing the process and showing light to the journey of revision of ICMR ethical guidelines. She informed that the ICMR guidelines are looked upon by researchers from all over the country, e.g. undergraduates, MD students, faculty members, institutional ethics committees and regulators as a gold standard. She expressed happiness since WHO and ICMR have closely worked together from many years to support the agenda of ethics.

Dr. Vijay Kumar, Head, Division of BMS, ICMR Headquarters, on behalf of Dr. Soumya Swaminathan, Secretary, DHR & DG ICMR**,** welcomed participants to ICMR–WHO regional consultation and thanked for sparing valuable time for this important activity of finalization of National Ethical Guidelines for Biomedical Research involving Human Participants. He said that these guidelines were posted

on the ICMR website and have received various comments and suggestions which are being incorporated. He also added up that today's deliberation will lead to further improvement and ultimately protecting rights, safety and well-being of human participants and also shared the video message of DG, ICMR.

Video message of **Dr. Soumya Swaminathan**, Secretary, DHR & DG ICMR**,** was played for the audience. She highlighted that as responsible citizens it is important to see that any research carried out in our country is governed by and follows the ethical guidelines. It is important to create awareness both for the researchers as well as the research participants. She said that it is important to incorporate the suggestions and comments in order to strengthen the draft and build consensus among all the stakeholders. She suggested the need of a dialogue process in the country for evolving new technologies and urged the participants to actively discuss and give their comments. She thanked all the participants for sparing their time and attending the regional consultation meeting.

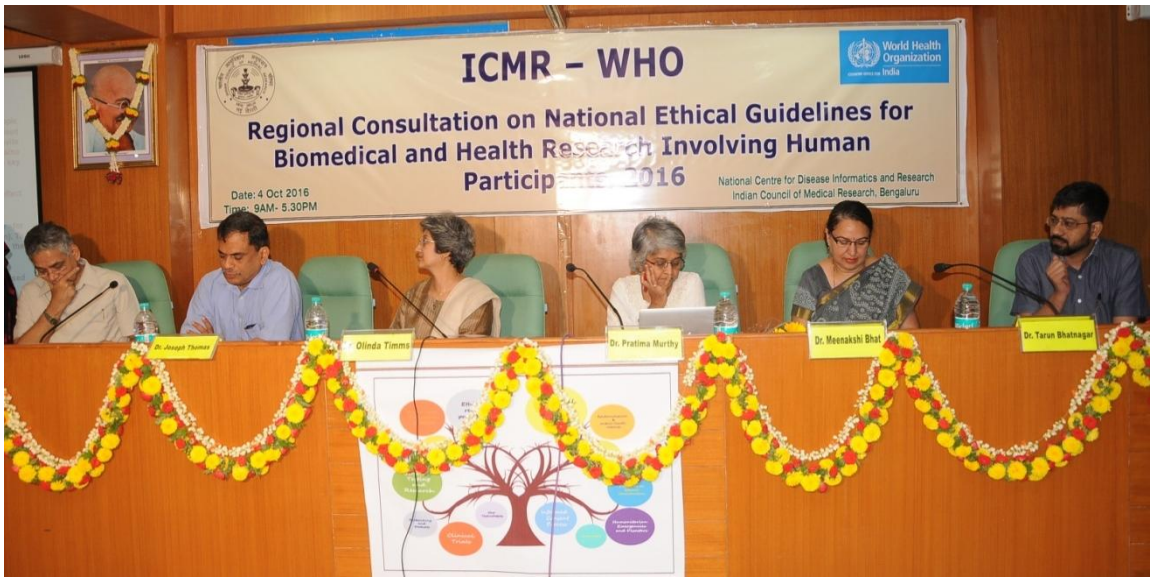
Dr. Roli Mathur, Scientist E and Head, ICMR Bioethics Unit, NCDIR, Bangalore, thanked the guests for gracing the occasion and for sharing their views and suggestions. She thanked DG ICMR, for encouragement and to the advisory group for providing direction and the forty six subcommittee members for their intellectual inputs in preparing the draft. She expressed her gratitude to Dr. Henk Bekedam, WHO representative, India and Dr. Madhur Gupta WHO representative, Country Office India for the technical collaboration with ICMR. She gave special thanks to the Division of Basic Medical Science, ICMR Headquarters, New Delhi. She also thanked all the staffs of NCDIR and ROHC for their keen help.

Panel Discussion I

General Ethical Issues, Informed Consent Process, Vulnerability

Chairperson: Dr. K K Talwar, Moderator: Dr. Joseph Thomas

Panelist: Dr. Olinda Timms, Dr. Pratima Murthy, Dr. Meenakshi Bhat, Dr. Tarun Bhatnagar



10-11.00 AM - Panel Discussion I: General Ethical Issues Informed Consent Process, Vulnerability

Chairperson: Dr. K. K. Talwar, Moderator: Dr. Joseph Thomas

Panelist: Dr. Olinda Timms, Dr. Pratima Murthy, Dr. Meenakshi Bhat and Dr. Tarun Bhatnagar

Dr. Joseph Thomas, Professor of Urology, Kasturba Medical College, Manipal, gave a brief overview for the panel discussion and thanked for being provided with an opportunity to share the views and comments on the various sections of the draft guidelines. He pointed out the concerns related to student's research as well as investigator initiated research and the role of institution. He suggested the need to find ways for the arrangement of corpus funds, payment of compensation, insurance coverage and for finding funds to adequately run student's research. He also suggested that the procedure to witness informed consent for research involving vulnerable participants could be explained in detail in the guidelines. **Dr. Olinda Timms,** Adjunct faculty, St. John's Research Institute, Bangalore, raised the issue about payment of compensation. She said that the decision about compensation should firmly be kept under the purview of the EC. The phases of clinical trials and types of adverse events or injury should be clearly defined in the guidelines. She also pointed out the need to have an appropriate mechanism for payment of insurance. She expressed concerns regarding the inclusion of economically disadvantaged, those with limited access to health care and adequate provisions for their protection. **Dr. Pratima Murthy**, Professor of Psychiatry, NIMHANS, Bangalore, said that presently there is no uniform system of training for researchers and EC members and therefore, the guidelines should indicate how the EC members should undergo a training. She raised her concerns regarding breach of confidentiality when there are risks to individuals. She felt that there was need for more clarity regarding the scientific and ethical review of research proposals. She suggested the use of term 'persons with mental illnesses in place of 'mentally ill' and 'spouse' in place of 'wife or husband or widows'. **Dr. Meenakshi Bhat,** Faculty, Centre for Human Genetics, Bangalore, pointed out the issues related to reconsent and revealing identity in the publication and to what extent identity can be revealed. She suggested that type of harms can also be legal and social. She also suggested that a proportion of budget or funding received by the Institution should be allocated to provide cover for insurance or payment of compensation. **Dr. Tarun Bhatnagar,** Scientist D, National Institute of Epidemiology (ICMR), Chennai, highlighted that according to CDSCO, audio visual recording of the process of oral consent is mainly applicable for clinical trials in vulnerable population; therefore, the use of AV recording for oral consent for research should be further clarified in the guidelines. He suggested

the need to elaborate and include the examples for explaining the test of understanding. He also suggested that templates for patient information sheet, checking for conflict of interest, etc. can be provided. **Dr. K. K. Talwar,** Department of Cardiology, Max Healthcare Pvt. Ltd., New Delhi, discussed the difficulties in the creation of corpus funds when medical institutions have very limited funds for research. It was suggested that research grants could help build a corpus and institutions should try to seek an insurance cover for all the research being conducted at the Institution. The issue of qualifications for chairperson of EC was discussed in detailed and it was suggested that she/he should have training and experience of being a member of EC though she/he may be from any background including medical/ non medical or legal.

General Suggestions & Recommendations:

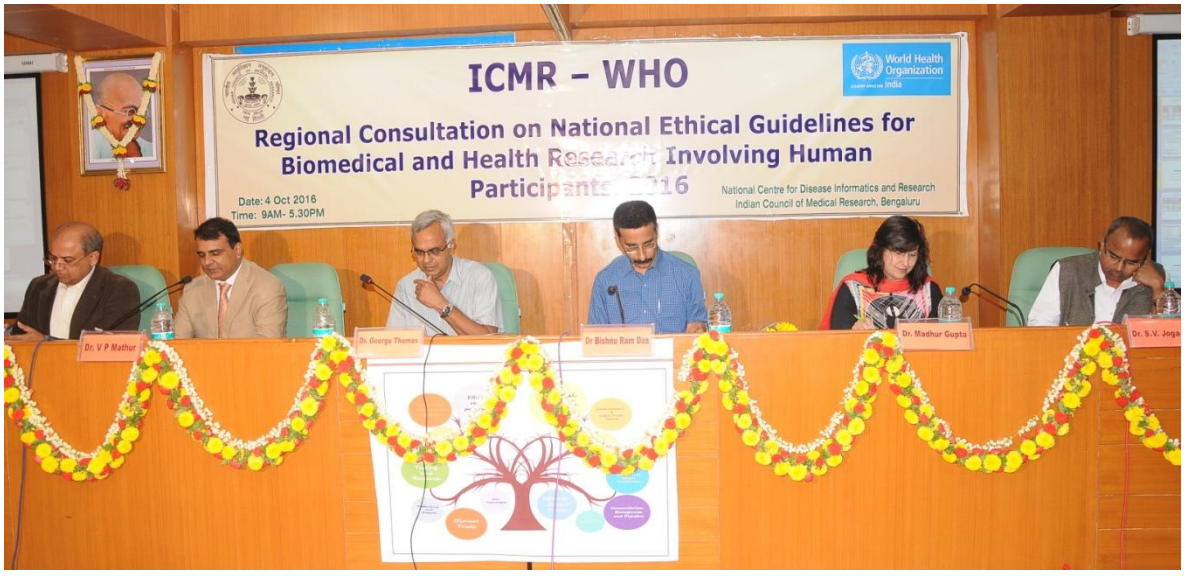
- The issue regarding principal investigator in academic research by students needs to be clarified in the guidelines.
- The responsibility of the institution and the policy of compensation in case of injury during research in academic institutions should be explained in detail.
- It was suggested that it is ideal for an institution to have a separate scientific committee besides the ethics committee, however, the ECs has every right to question the scientific validity even if the scientific committee has approved the study if it concerns the rights, welfare and safety of research participants.
- In addition to the physical harms of participation in research, there can also be legal and social harm and these can be described in the guidelines.
- The need and process for continuing review or reporting for SAEs for clinical trial or academic studies should be clearly mentioned.
- The guidelines should outline the various provisions for appealing against the EC decision or suggestion by the investigator.
- The details of the appellate authority need to be clarified and given in more detail for follow-up at various institutions.

Panel Discussion II

Ethical Review Procedures

Chairperson: Dr. Alok Srivastava, Moderator: Dr. Vijay Prakash Mathur

Panelists: Dr. George Thomas, Dr Madhur Gupta, Dr. Bishnu Ram Das, Dr. S.V. Joga Rao



11 AM-12.00 Noon - Panel Discussion II: Ethical Review Procedures

Chairperson: Dr. Alok Srivastava, Moderator: Dr. Vijay Prakash Mathur

Panelists: Dr. George Thomas, Dr. Madhur Gupta, Dr. Bishnu Ram Das and Dr. S.V. Joga Rao

Dr. V. P. Mathur, Additional Professor, Pedodontics and Preventive Dentistry, Centre for Dental Education and Research, All India Institute of Medical Sciences, New Delhi, suggested that the templates for SOPs can also be developed by ICMR as these would help researchers. Scope of the guidelines should be separately explained for clinical trials and for academic studies. Some guidance or SOPs should also be provided regarding membership which clarifies that all the members of EC should not be changed at the same time. About 30-50% of members may be changed to ensure continuation and proper functioning of ethics committees. **Dr. George Thomas,** Chief Orthopaedic Surgeon, St. Isabel's Hospital, Chennai, said that the independent or for profit ECs exists and these are not a very feasible model since these encourage EC shopping. Instead bigger medical institutions should have provision to review research proposals from smaller set ups. He suggested possible collaboration between ICMR and MCI for establishing medical research unit in all medical colleges across the country. **Dr. Madhur Gupta,** Technical Officer-Pharmaceuticals, WHO Country Office for India, stressed about the need for building capacity and providing infrastructure to EC in the type B and C cities, since so far required supports have not been provided to them. She suggested that templates for SOPs and terms of reference should also be included in the guidelines. She also suggested that guidelines for biosimilars should be expanded and added as an annexure to the guidelines. **Dr. B. R. Das,** Associate Professor, Dept. of Community Medicine, Jorhat Medical College, Jorhat, Assam, appreciated the revised guidelines. He raised concerns about ensuring confidentiality of the data since it is accessible to EC secretariat staff. He pointed out that sometimes researchers do not submit all the required documents to the ECs which delays ethical review and therefore, the use of checklist should be encouraged. He also stressed on the need for capacity building of the ECs and researchers. **Dr. S. V. Joga Rao**, Additional Professor, National Law School of India University, Bangalore, discussed the need to focus and strengthen the role of legal expert or lay person in EC meeting as they are the public voice. He stated that sometimes researchers do not co-operate for continuous review or for being monitoring by the ECs and therefore, guidelines should clearly describe the processes in detail. **Dr. Alok Srivastava,** Professor, Department of Haematology, Christian Medical College, Vellore,

discussed the role of ECs in detail and suggested that ECs should discuss about science and ethics both while reviewing research proposals.

General observations & recommendations:

- The ECs should review both ethical and scientific aspects of research.
- Documents related to EC functioning should be prepared; templates, drafts, TOR's, specific SOP's for receiving/ review/ replying and conduct of EC meetings, sample forms, COI declaration forms, confidentiality agreements for EC members and secretarial staff.
- Role and functions of independent ECs needs to be elaborated.
- The required and desirable qualification of each EC member can be given in one table and desired roles/ duties of each member may be elaborated upon.
- Not more than 50% of EC members should be replaced within a short span of time (3 to 6 months).
- New members of EC should attend initial meetings as guest observers for orientation before they become voting members of EC.
- EC should specify the duration of approval for study. It may grant approval for full duration of the study, subject to timely submission of annual reports. In case of non submission of progress report, the EC should revoke its approval.
- Experts can join the meeting via video/tele conferences for opinion.
- Archiving and record keeping can be carried out in electronic format.

Panel Discussion III

Epidemiological, Public Health, Socio-Behavioral Sciences, Humanitarian Emergencies/ Disasters Research

Chairperson: Dr. NK Arora, Moderator: Dr. Mala Ramanathan

Panelist: Dr. M. K. Sudarshan, Mr H. L. Gundu Rao, Dr Dorothy Lall and Dr Ragini Kulkarni

12-1:00PM - Panel Discussion III: Epidemiological, Public Health, Socio-Behavioral Sciences, Humanitarian Emergencies/ Disasters Research

Chairperson: Dr. NK Arora, Moderator: Dr. Mala Ramanathan

Panelist: Dr. M. K. Sudarshan, Mr H. L. Gundu Rao, Dr. Dorothy Lall and Dr. Ragini Kulkarni

Dr. Mala Ramanathan, Professor, AMCHSS, Sree Chitra Tirunal Institute for Medical Sciences and Technology (SCTIMST), Thiruvananthapuram, pointed out the importance of identifying the ethical issues in public health research and quantitative research so that such research is responsive to the health needs of our population. **Dr. M. K. Sudarshan,** Professor and Head, Rajiv Gandhi Institute of Public Health, Rajiv Gandhi University of Health Sciences, Bangalore, suggested that the templates for the review of socio-behavioral research studies should be included in the guidelines. **Dr. Dorothy Lall,** Institute of Public Health, Bangalore, highlighted that studies which fall in the interface of public health research and use social science methods for research needs to be elaborated in the guidelines. She also suggested that plan for dissemination of results should be included beforehand. There should be full review for studies involving mild deception. Examples for Etic and Emic issues should be explained in detail. **Dr. H. L. Gundu Rao**, Legal expert, Bangalore, focused on interpersonal relationship and suggested linkages between community, service provider and researcher. **Dr. N. K. Arora,** Executive Director, The INCLEN Trust International, New Delhi, discussed the importance of ethics committees review even at the surveillance site and also discussed about ethical aspects of implementation research.

General observation and recommendations:-

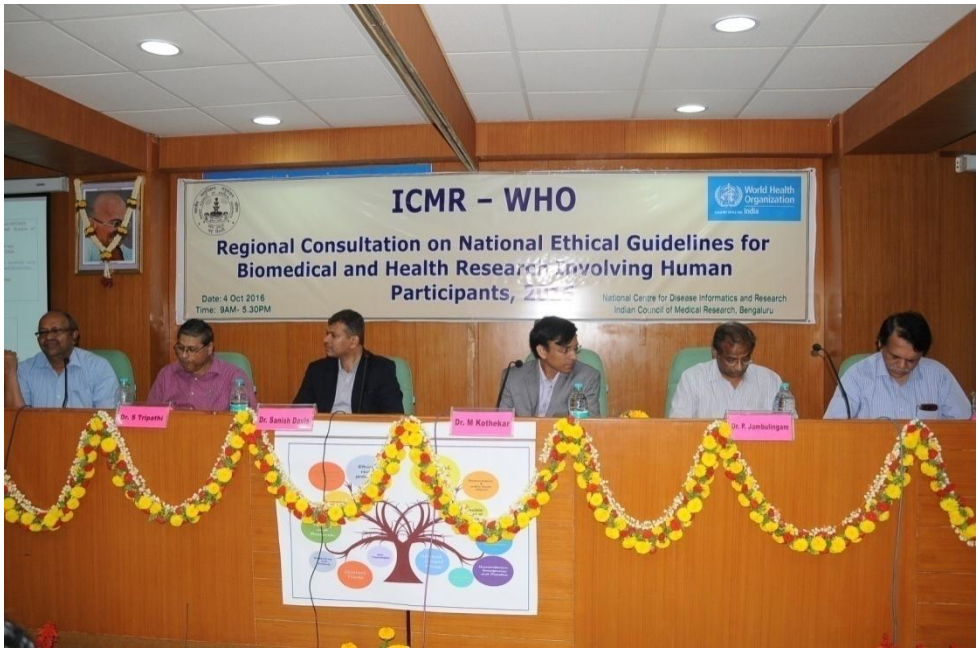
- The need for community advisory board and its role may be stressed upon in the guidelines.
- The role of head of community to be emphasized along with the role of social activist and other community representatives.
- The return of results or benefit sharing to the community should be an essential component of Public Health research which involves communities.
- The safety of research team is important in public health research and should be built in to the research design.
- New drug intervention in cohort studies can be addressed in more detail in the guidelines.

Panel Discussion IV

Clinical trials of drugs and other interventions and New Technologies

Chairperson: Dr. G K Rath, Moderator: Dr. Santanu Tripathi

Panelist: Dr. Sanish Davis, Dr. P. Jambulingam, Dr. Mudgal Kothekar, Dr. P. Satish Chandra



2-3.00 PM: Panel Discussion IV - Clinical trials of drugs and other interventions and New Technologies

Chairperson: Dr. G K Rath, Moderator: Dr. Santanu Tripathi

Panelist: Dr. Sanish Davis, Dr. P. Jambulingam, Dr. Mudgal Kothekar, Dr. P. Satish Chandra

Dr. Santanu Tripathi, Professor and Head Clinical and Experimental Pharmacology, Calcutta School of Tropical Medicine, Kolkata, stated that therapeutic misconception can be elaborated upon in the guidelines. He suggested that the qualification of the study team in the specialized area on which the trial is planned should be elucidated. PI's qualification for the acceptance of study should also be addressed. **Dr. Sanish Davis,** Country Head, Covance India Pharmaceutical Services Pvt. Ltd., Mumbai informed that ICMR Guidelines are considered as quasi judicial. He discussed about the validity of study duration and timelines for SAE reporting. Post trial access should be addressed before initiation of study. **Dr. Mudgal Kothekar**, Medical Director, Biocon, Bangalore, emphasized the issues of post trial access, SAE reporting, standard of care, oncology clinical trials and publication ethics in detail. **Dr. P. Jambulingam,** Scientist G & Director, Vector Control Research Centre, Puducherry, raised the issue of providing an insurance cover for community based clinical trials and other unrelated illnesses. He discussed regarding the payment of compensation and suggested that clear guidance for ECs should be given in the guidelines. **Dr. P. Satish Chandra,** Senior Professor, Department of Neurology**,** NIMHANS, Bangalore, discussed the issues related to multicentric clinical trials, major and minor protocol deviation, reporting of death, SAE, removal of internal device and sham surgery etc. He suggested that surgical clinical trials should also be registered. The differences between the regulatory and non regulatory clinical trials were also discussed. **Dr. G. K. Rath,** Professor and Head, Department of Radiation Oncology and Chief, Institute Rotary Cancer Hospital, All India Institute of Medical Sciences, New Delhi, appreciated ICMR's initiatives for addressing the emerging ethical challenges posed by the recent development in biomedical and health research.

General observation and recommendations

- Therapeutic misconception in potential participants must be avoided and the guidelines should give more details on this.
- It was suggested that at least one member of the research team should have qualification in the subject area in which the trial is planned.
- Issues related to SAE reporting and its timeline should be clearly

outlined.

- Site specific protocol modifications and post trial access should be elaborated upon in the guidelines.
- It was suggested that the procedure of EC approval for multicentric clinical trials may be clarified.

- Publication of site specific data needs to be addressed in more detail in multicentric clinical trials.

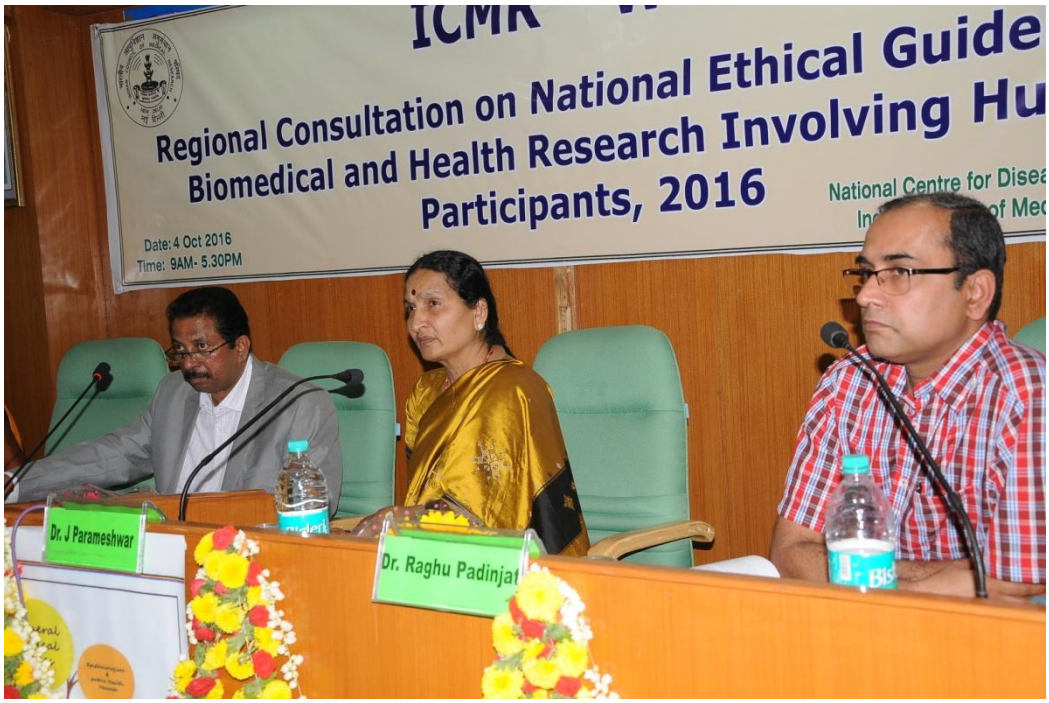
- Clinical trials involving surgical interventions and those using radiology can also be included as separate sections.

Panel Discussion V

Human Genetics Testing and Research, Biological materials, Biobanking and Datasets

Chairperson: Dr. H Sharat Chandra, Moderator: Dr. Manjulika Vaz

Panelist: Dr. Janet Parameshwar, Dr. Raghu Padinjat, Dr Jayarama S Kadandale



3-4.00 PM: Panel Discussion V - Human Genetics Testing and Research, Biological materials, Biobanking and Datasets

Chairperson: Dr. H Sharat Chandra, Moderator: Dr. Manjulika Vaz

Panelist: Dr. Janet Parameshwar, Dr. Raghu Padinjat, Dr. Jayarama S Kadandale

Dr. Manjulika Vaz, Lecturer, Health and Humanities Division, St. John's Research Institute, Bangalore, said that distinction between genetic services and research should be further clarified. **Dr. Jayaram Kadandale,** Head, Clinical & Molecular Cytogenetics, Centre for Human Genetics, Bangalore, highlighted the precautions to be taken for non invasive prenatal testing and reporting by in-house testing centers. **Dr. Janet Parameshwar,** Social Welfare Officer, Kidwai Memorial Institute of Oncology, Bangalore, said that confidentiality should be maintained and any claims for benefits of research also be examined and monitored. **Dr. Raghu Padinjat,** Associate Professor, National Centre for Biological Sciences, Bangalore, said that greater attention must be given Biological Sciences, Bangalore, said that greater attention must be given about how to deal with the ethical issues related to the new technology such as CRISPR. There should be distinction between research carried out using human samples freshly derived from patients and human derived established cell lines (immortalized cell lines from ATCC (American Type Culture Collection)). **Prof. H. Sharat Chandra,** Honorary Director, Centre for Human Genetics, Bangalore, discussed the concerns related to confidentiality/ privacy of the genetic data and the difficulty to maintain complete confidentiality of information. He also pointed out that genetic services and research cannot be separated from one another. He suggested that training, accreditation facilities and review of certified labs are important.

General observation and recommendations:-

- While reviewing genetic research protocols or monitoring such studies, a competent person in human genetics could be invited to attend the EC meeting as a nonvoting expert.
- ICMR can set up regional advisory cells in the country to guide ECs and institutions.
- Detailed guidelines for genetic testing, in terms of quality control, manpower training, interpretation of results and counseling are required.
- Governance committee of biobanks to have a representation of community members, lay members and other stakeholders.

Panel Discussion VI

International Collaboration, Responsible Conduct of Research

Chairperson: Dr. R C Mahajan, Moderator: Dr. Siddhartha Laskar

Panelist: Dr. Pradeep Menon, Dr R.R. Gangakhedkar, Dr. G D Ravindran

4-4:30 PM: Panel Discussion VI – International Collaboration, Responsible Conduct of Research

Chairperson: Dr. R C Mahajan, Moderator: Dr. Siddhartha Laskar

Panelist: Dr Pradeep Menon, Dr R.R. Gangakhedkar, Dr. G D Ravindran

Dr. R. C. Mahajan, Emeritus Professor, Department of Parasitology, Postgraduate Institute of Medical Education & Research, Chandigarh, emphasized that Indian partners should understand that they are equal partners for international collaboration research and collection of samples and storing. Responsible Conduct of Research (RCR) should be clearly part and parcel of every research study. **Dr. Siddhartha Laskar,** Professor, Dept. of Radiation Oncology, Tata Memorial Hospital, Mumbai, discussed about streamlining the HMSC submission and clearance process. **Dr. Pradeep Menon,** Scientist E, National Institute for Research in Tuberculosis, Chennai, raised the issues related to ghost authorship and sharing of cloud data. **Dr. R. R. Gangakhedkar,** Scientist F & Director-in-charge, National AIDS Research Institute, Pune, emphasized the oversampling of vulnerable populations, e.g., anti-retroviral therapy. He was also of the opinion that there should be clarity in the types of collaboration and online data sharing. **Dr. G. D. Ravindran,** Professor and Head, General Medicine, St. John's Medical College, Bangalore, stated the need to have a separate section on electronic data. He said that standard of care should be given to the research participants. He also pointed out the difficulties in the coordination between various ECs of all the study sites.

General observation and recommendations:-

- Guidance on constituting technical authorization committees, governance committees for biobanks and drafting of Material Transfer Agreement (MTA), Data Transfer Agreement (DTA), etc. is required.
- Appropriate policy is required for international transfer of data or samples, pooling of resources and technology transfer.

ICMR –WHO National Consultation

On

"National Ethical Guidelines for Biomedical and Health Research involving Human Participants"

At

Indian Council of Medical Research

14th December, 2016, New Delhi

Proceedings of the National Consultation Meeting

Welcome and Opening Remarks

Welcome and Opening Remarks

Dr. Roli Mathur, Scientist-E and Head, ICMR Bioethics Unit, NCDIR, Bangalore, welcomed all the invited guests. She said that the National Consultation meeting is organized in collaboration with WHO country office India, to reach out to the larger panel of national experts and to seek their comments on the revised ethical guidelines and to get final approval before the document goes for printing. ICMR ethical guidelines hope to provide an answer to deal with the emerging ethical challenges and to be a reference point for biomedical and health research in India. She stated that it is an important day when we are closing the process of consultation of revised ethical guidelines which was initiated in early August, 2016. She welcomed members of CECHR, all the chairs and representative of various government departments, ministries, agencies and councils as well as members of international organizations, directors and faculties of institutions, non government organization, hospitals and associations etc. She also said that the revised guidelines has received positive feedback and this document once released will set standards not only in India but across the globe. A very large number of persons have contributed to the development of the guidelines; to which ICMR is thankful. She informed that when the document was posted on the ICMR website for public comments, almost 1,324 comments were received from individuals, institutions and agencies. The five sections of earlier 2006 guidelines have been extended to 13 different sections.

Remarks by Co- Chairperson, Advisory Group

Dr. S. D. Seth, Co- Chairperson, advisory group committee gave a brief account of the revision of ICMR Ethical Guidelines from 1980 to 2016. ICMR brought out the 'Policy Statement on Ethical Considerations involved in Research on Human Subjects' in 1980 under the chairmanship of Justice H R Khanna, these guidelines were revised in 2000 as the 'Ethical guidelines for Biomedical Research on Human Subjects' under the chairmanship of Justice MNR Venkatachaliah. In view of the new developments in the field of science and technology another revision was carried out as Ethical Guidelines for Biomedical Research on Human Participants in 2006. He said that 12 subcommittees were formed with experts and meetings were held to finalize the zero drafts of the sections for the revised guidelines. Zero drafts were further edited and finalized by advisory group members in several meetings throughout the year. He said that after finalizing the draft guidelines, it was posted on the ICMR website for public consultation and comments were invited from various stakeholders. The draft guidelines were also sent to various organizations like DBT, DST, and AYUSH for critical comments. A large number of comments have been received from approximately 63 individuals as well as organizations, valuable comments from national and international agencies like NIH and OHRP has also been received.

Following the suggestions received, the draft guidelines have been further revised.

Remarks by Advisory Group

The Advisory group members Dr. Nandini K Kumar, Dr. N. K. Arora, Dr. Urmila Thatte and Dr. Vijay Kumar discussed on the various sections which were taken care and the various changes made in each section under their supervision. The new guidelines contains 13 sections with separate sections on; Informed Consent Process, Vulnerability, Social and Behavioral Sciences Research for Health, Biological materials, Biobanking and Datasets, International Collaboration, Research during Humanitarian Emergencies and Disasters and Responsible Conduct of Research. The advisory group members thanked all the stakeholders for critically reviewing the draft guidelines and suggesting the necessary changes. They also thanked DG, ICMR for providing the opportunity for revising the ICMR Ethical Guidelines as advisory group members.

Remarks by Country Representative, WHO India

Dr. Henk Bekedam, WHO Representative, Country Office for India said that it has been a privilege to have closely worked with ICMR for supporting the agenda of ethics. The draft ethical guidelines have addressed the emerging issues and discussed the importance and need for setting up the ethical standard for research in India. He also informed everyone about the plan to develop online courses for ethics committees jointly by ICMR and WHO.

Remarks by DG ICMR

Dr. Soumya Swaminathan, Secretary, DHR & DG ICMR, welcomed the guests and thanked them for sharing their valuable time. She congratulated all the advisory group members for their efforts and also thanked WHO for their support to organize the consultation meetings for finalizing the draft guidelines. She discussed some of the important sections of the revised draft guidelines and highlighted the new additions to the guidelines that have been incorporated. She discussed the importance of online course on ethics and suggested to pursue it at the earliest.

Vote of Thanks by Dr. Roli Mathur

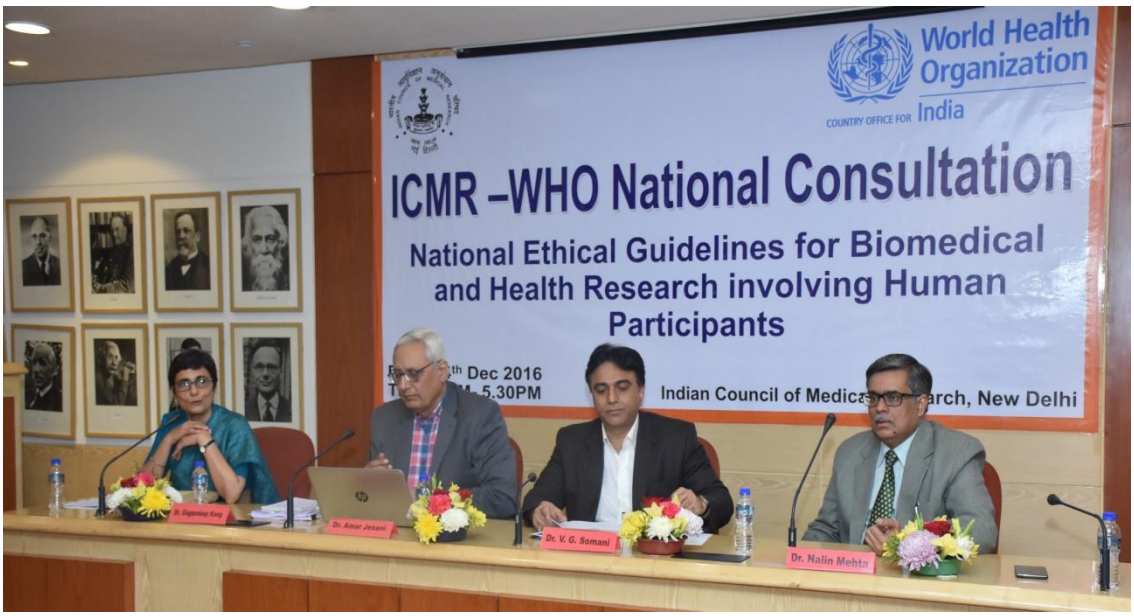
Dr. Roli Mathur thanked the invited guests for gracing the occasion, DG ICMR, Dr. Henk Bekedam, Dr. Madhur Gupta, all the advisory group members, subcommittee members and many others, both scientific as well as administrative support towards the finalization of the draft ethical guidelines.

Panel Discussion I

General Ethical Issues, Informed Consent Process, Vulnerability

Chairperson: Dr. Gagandeep Kang

Panelist: Dr. Amar Jesani, Dr. V. G. Somani, Dr. Nalin Mehta



10-11.00AM - Panel Discussion I - General Ethical Issues, Informed Consent Process & Vulnerability

Chairperson: Dr. Gagandeep Kang

Panelists: Dr. Amar Jesani, Dr. V. G. Somani and Dr. Nalin Mehta

Dr. Gagandeep Kang, Executive Director, Translational Health Science and Technology Institute (THSTI), Faridabad, discussed the differences in the process of informed consent at different research set ups. She explained how conduct of research differs at hospital or at the community level and what should be the process of obtaining the informed consent while protecting vulnerable population at these set ups. She also discussed about the need for teaching ethics to researchers and providing training to ECs. She pointed out need to protect the vulnerable populations and suggested ways of conducting the studies that involve inclusion of pregnant women or other tribal groups in research. **Dr. Amar Jesani,** Editor, Indian Journal of Medical Ethics, Mumbai, discussed about the issues related to benefit-risk analysis, privacy–confidentiality, selection of participants and monitoring of research. He suggested that priorities should be given to these issues in the guidelines. Role of audio and visuals aids at the time of data collection (privacy and confidentiality of participants), undue inducement, payment for participation, etc. should be clearly defined in the guidelines. This guideline may provide information as to who obtains the informed consent and where it is taken. Role of gatekeepers should be clearly defined especially when vulnerable populations are involved. **Dr. V G Somani,** Joint Drugs Controller, Ministry of Health and Family Welfare, Government of India, New Delhi, emphasized the need to simplify the language used in the guidelines so that it can be easily read by the patients and common people. He discussed about the role of treating physician as PI and when informed consent is obtained by the treating physician. He said that the mechanism of compensation should be smooth and details needs to be provided in the protocol. **Dr. Nalin Mehta,** Professor, Dept. of Physiology, AIIMS, New Dehli, discussed about post trial access to the patient, the magnitude of probable risk and definition of minimal risk. He suggested that the post trial access to the patient should be built in to the study.

General Suggestions & Recommendations:

- ECs should carefully review proposals that involve research on vulnerable populations.
- Investigators should adequately justify the exclusion or inclusion of vulnerable populations in the protocol.
- There should be ways to ensure

safety of vulnerable population groups and protection of their confidential information.

- Details regarding payment of compensation for research related injury should be provided in the informed consent form.
- Clear distinction should be made between vulnerable and specific populations to be involved in research in the guidelines.

Panel Discussion II

Ethical Review Procedures

Chairperson: Dr. Kusum Verma

Panelists: Dr. Madhur Gupta, Dr. Sita Naik, Dr. Prabha Desikan, Ms. Annam Visala

11 AM - 12.00 Noon-Panel Discussion II - Ethical Review Procedures

Chairperson: Dr. Kusum Verma

Panelists: Dr. Madhur Gupta, Dr. Sita Naik and Dr. Prabha Desikan

Dr. Kusum Verma, Senior Consultant, Department of Pathology, Sir Ganga Ram Hospital, New Delhi, stated that in the revised guidelines, this section has been done quite well compared to earlier document. She suggested that addendums to guidelines should be brought out every six months or in an interval of one year as per need, members of EC should be trained and; training programs must be introduced for EC members and researchers. **Dr. Madhur Gupta,** Technical Officer-Pharmaceuticals, WHO Country Office for India described the online course for ethics committee members which is being developed by National Institute of Epidemiology (ICMR). She spoke about payment of compensation and its importance in case of research related injury. She suggested that the word 'may' can be changed to 'should/shall' in the sentence "Ethics Committees 'may' suggest appropriate compensation" as the ethics committees are empowered to take decision on compensation. **Dr. Sita Naik,** Advisor, Apollo Hospitals Educational & Research Foundation, Apollo Indraprastha Hospital, New Delhi, spoke on benefits and risk analysis. She discussed about the following parameters - assessment of benefits and risk to the patients; innovation and existing therapeutic options and unmet medical health of the people. She highlighted that innovation and existing therapeutic options have become an issue, as lot of drugs coming of today are variations of existing molecules which have limited amount of implemental benefit over the existing molecules. She also spoke on the importance of training, periodic certification and retraining on ethics. **Dr. Prabha Desikan,** Director-in-Charge, Professor and Head, Microbiology, Bhopal Memorial Hospital & Research Centre, Bhopal, stated that the roles of each member have been defined quite well in this draft guideline. She also spoke on the importance of expedited review procedure and the need to implement training programmes in research institutes. **Ms. Annam Visala**, Deputy Drugs Controller, Ministry of Health and Family Welfare, Government of India, New Delhi, highlighted that the benefits and risk, compensation, roles and responsibilities of chairman of EC and expedited review procedure has more clarity as compared to the previous document. She suggested putting a sub topic on role of expert in the committee, conflict of interest that they might bring in, funding for the ethics committee and institution responsibilities for providing infrastructures, funding and independence to the ethics committees to function as independent organizations.

General Suggestions & Recommendations:

- It was suggested that addendums can be brought out to the revised ethical guidelines by ICMR every six months or in an interval of one year as per need.
- Training programs must be introduced for all members of EC.
- Specific role of experts in the committee should be discussed in the guidelines.
- Institution's responsibilities for providing infrastructures, funding and independence to the ethics committees to function as independent organizations should be clearly defined as this would help improve EC functioning.

Panel Discussion III

Public Health Research, Socio-Behavioral Sciences, Humanitarian Emergencies/ Disasters Research

Chairperson: Dr. Sanjay Mehendale

Panelist: Dr. Amita Singh, Dr. Ravi Verma, Dr. Sanghamitra Pati

12-1.00 PM-Panel Discussion III - Public Health Research, Socio-Behavioral Sciences, Humanitarian Emergencies/ Disasters Research

Chairperson: Dr. Sanjay Mehendale
Panelists: Dr. Amita Singh, Dr. Ravi Verma and Dr. Sanghmitra Pati

Dr. Sanjay Mehendale, Additional DG, ICMR, New Delhi, raised the issue regarding the use of newer technology such as imaging and hand held devices etc. which may bring out ethical issues related to breach of confidentiality and therefore, need appropriate guidance. In public health research, some emphasis is required on screening of populations. He spoke about concerns related to biobanking; tissue banking especially in community settings where they have different sets of moral and ethical concerns. He also discussed the basic difference between public health programs and research and both should be clearly defined in the introduction. He discussed on sensitivities related to social science research, socio-behaviour research, disaster and public heath emergencies and said that the focus of public health functionaries are directly related to providing relief. Methodology and concerns related to collection of information through surveillance, specific reference to control of outbreaks, or listening to people with some specific set of complaints, sensitive information, etc. is important. **Dr. Amita Singh,** Professor, Centre for the Study of Law and Governance, Jawaharlal Nehru University, New Delhi, said that ethics is inseparable from social sciences. She spoke on the impact and differences between social sciences and natural sciences. She also pointed out the ethical issues related to the questionnaire based research on research participants after humanitarian emergencies and disasters. **Dr. Ravi Verma,** Regional Director, Asia Regional Office, International Center for Research on Women's (ICRW), New Delhi, spoke on the specificity in newer areas of social science research. He spoke on the various areas of social and behavioral research such as violence against women, child sex abuse research and child marriage to be addressed in the ethical guidelines and how the risk assessment should be done to deal with these issues**. Dr. Sanghamitra Pati,** Director, Regional Medical Research Centre, Bhubaneswar, spoke on the overlap between the clinical, public health, social and behavioral research**.** She said that equitability is one of the principles of ethical research. She also spoke on the involvement of physically and mentally challenged people in research.

General Suggestions & Recommendations:

- Various areas of social and behavioral research such as violence against women, child sex abuse research and child marriage to be taken as an issue in the ethical guidelines.
- The differences and requirements for public health programs and public health research should be clarified.
- The guidelines should discuss ways of dealing with sensitive information.
- Guidelines for social science research are important and should be discussed in detail.

Panel Discussion IV

Clinical trials of drugs and other interventions

Chairperson: Dr. Y. K. Gupta

Panelist: Dr. V. G. Somani, Dr. Arun Bhatt, Dr. Upendra Kaul

2-3.00 PM-Panel Discussion IV - Clinical trials of drugs and other interventions

Chairperson: Dr. Y. K. Gupta
Panelist: Dr. V G Somani, Dr. Arun Bhatt and Dr Upendra Kaul

Dr. Y K Gupta, Professor and Head, Department of Pharmacology, AIIMS, New Delhi, raised the need to have clear definitions for clinical trials, regulatory/ non-regulatory and academic/ non-academic clinical trials. He also discussed about the role of ECs in the assessment and documentation of causality of research related injuries or harm. He highlighted the importance of looking at the qualifications of investigators discussing whether postgraduate students can be an investigator or not. It was felt that there is a need to assess the competence of investigator. He highlighted the difficulties in assessment or documentation and reporting of SAE/ AE. Since the compensation is decided by the ECs there is need for proper training for EC members. He also discussed regarding the mechanism of handling patients outside the hospital for SAE. **Dr. Arun Bhatt,** Representative, Indian Society for Clinical Research, Mumbai, discussed about the qualifications and research experience of PI in the conduct of clinical trials. He suggested that vulnerable populations and their safety in trials should also be considered. **Dr. Upendra Kaul,** Executive Director and Dean-Cardiology, Fortis Escort Heart Institute, New Delhi, discussed about whether compensation should be given to the injury occurred due to trial or during the trial. Therefore, the mechanism of causality assessment should be in place to calculate the quantum of compensation for research related injury. **Dr. V. G. Somani,** Joint Drugs Controller, Ministry of Health and Family Welfare, Government of India, New Delhi, discussed the issue of payment of compensation in case of injury during research. He highlighted the need for harmonization of ICMR guidelines with the regulations.

General Suggestions & Recommendations:

- It was suggested that there is a need to synchronize the regulatory requirements in accordance to the ethical guidelines for clinical trials.
- The ethical guidelines set standards and the regulations should consider these while planning amendments in the regulations.
- Structured training of EC members including the procedure for the calculation of amount of compensation and assessment of causality for SAE is required.
- There is a need for continuing review by ECs for high risk trials and should be included in the guidelines.

Panel Discussion V

Human Genetics Testing and Research, Biological materials, Biobanking and Datasets

Chairperson: Dr. N. K. Mehra

Panelist: Dr. Poonam Salotra, Mr. Prasanna Kumar B Shirol, Dr. Ratna Puri

4.00 PM- Panel Discussion V - Human Genetics Testing and Research, Biological materials, Biobanking and Datasets

Chairperson: Dr. N. K. Mehra

Panelist: Dr. Poonam Salotra, Mr. Prasanna Kumar B Shirol and Dr. Ratna Puri

Dr. N. K. Mehra, Dr. C. G. Pandit National Chair ICMR and Former Dean & Head, Department of Transplant Immunology & Immunogenetics, AIIMS, New Delhi, appreciated the contents of the genetics section in the guidelines and said that it has covered almost every issues related to genetic testing and research. He suggested that the guidelines should be crisp and extensive details or repetitions should be avoided. He highlighted the ethical issues related to genetic testing and genetic research which are of concern across the country. He also spoke on the issues related to innovative testing for prenatal diagnosis and adoption under genetic testing. **Dr. Ratna Puri,** Senior Consultant, Institute of Medical Genetics & Genomics, Sir Ganga Ram Hospital, New Delhi, highlighted the practical issues for obtaining fresh consent from patients for publication of photographs. She suggested that all the relevant information regarding publication should be provided to patient while obtaining consent, e.g. taking a photograph for genetic research. She also suggested that for protecting patient's privacy and confidentiality, mobile camera should not be used for taking photographs and only hospital camera should be allowed. She discussed that the ethical issues related to carrier testing and new born screening are covered in the guidelines. She raised the issue regarding secondary use of archived sample and suggested that archived samples should be partially or fully anonymised for rare disease research. **Dr. Poonam Salotra,** Scientist G & Director-in-charge, National Institute of Pathology, New Delhi, discussed about the data ownership and authorization for archived samples. She raised the issues related to commercialization of biobanking, datasets and quality assurance for biobanking. **Mr. Prasanna Kumar B Shirol,** President-Pompe Foundation, Bangalore, highlighted the issues related to small scale research set up and research for rare genetic disorders. He discussed about the need for an insurance coverage for genetic and long term disorders, the issues related to genetic testing, gene editing and designer babies. The issues of community consent, group consent and reconsent were also discussed in detail.

General Suggestions & Recommendations:

- It was suggested that consent should be obtained even for routine genetic testing.
- Genetic research and testing are

often overlapping and therefore, need due care.
- Data ownership and authorization for archived samples should be clearly mentioned.

- Reconsent for use of research participant's data for publication and teaching purpose should be clearly mentioned in the guidelines.

Panel Discussion VI

International Collaboration, Responsible Conduct of Research

Chairperson: Dr. Indira Nath

Panelist: Dr. T. S. Rao, Dr. Anant Bhan, Dr. Nithya Gogtay

4-4.30 PM -Panel Discussion VI - International collaboration and Responsible Conduct of Research

Chairperson: Dr. Indira Nath

Panelist: Dr. T S Rao, Dr. Anant Bhan and Dr. Nithya Gogtay

Dr. Indira Nath, former Emeritus Professor, Raja Raman Fellow, National Institute of Pathology, New Delhi, congratulated ICMR for bringing out the wonderful document. She pointed out how these guidelines will help the Indian investigators for international collaboration. She also pointed out the importance of capacity building to increase awareness. **Dr. T S Rao,** former Senior Advisor, Department of Biotechnology, also complemented ICMR for preparing the very comprehensive document. He emphasized the issue regarding technology transfer and IPR for sharing data. He also suggested that a paragraph on the role of sponsor in the international collaboration section should be added. He suggested that references regarding biosafety and biodiversity can also be included. He said that the IPR and data sharing issues should be clearly defined along with the role of ECs and funding agencies. **Dr. Anant Bhan,** Senior Manager, International AIDS Vaccine Initiative (IAVI), India Regional Office, New Delhi, specified that India is a major partner in an international collaboration where countries with poor resource than India are involved. Therefore, the guidelines should reflect the responsibility to protect other partners or collaborators. He pointed out that there is a need to make the HMSC process more efficient. He was of the opinion that responsible conduct of research is about responsible investigator. He raised the issue of protection of whistle blowers. He suggested that the time frame of data sharing needs to be mentioned as well as the issues pertaining to parachute research. **Dr. Nithya Gogtay,** Additional Professor of Clinical Pharmacology, Seth GS Medical College & King Edward Memorial Hospital, Mumbai, suggested including the definitions of international collaboration and responsible conduct of research at the beginning of the respective sections. The importance of international collaboration and issue of different views of ECs within the country in multicentric trials needs to be mentioned. She stressed that the research cell or research secretariat should have standard operating procedures (SOPs) to address all the major components, e.g. values, policies, planning, conduct, etc. Mentor should devote sufficient time towards their mentees and improve quality of output from research. SOPs for the protection of whistleblower are important and should be included.

General Suggestions & Recommendations:

- It was suggested that the title of the section international collaboration

may be changed to collaborative research.

- The roles and responsibilities of funder and sponsor should be differentiated clearly.

Concluding Remarks:

Dr. P. N. Tandon, Chairperson, Central Ethics Committee on Human Research (CECHR), discussed the journey of ICMR guidelines from 2006, and the preparation of the Draft of Ethics bill in the year 2013-2014 and its subsequent submission to the Government for considerations of conversion to legislation. He informed the importance of the guidelines for research in India keeping in view of the social, cultural, economic and religious aspects of our country. He also emphasized on the need for capacity building in the field of ethics in the country.

Dr. G. N. Singh, Drugs Controller General of India**,** mentioned that this document will be useful to the country and will help to strengthen the ethics committee perform their duties and thereby help the regulators. He suggested that the document should be prepared in simple language so that it is very easy to understand.

Dr. Soumya Swaminathan, DG ICMR, expressed her happiness and thanked all the experts for actively participating and giving the inputs for finalization of the Draft National Ethical Guidelines. ICMR has made all efforts to engage with public as well as experts and stakeholders in order to bring in transparency and to have opinion from all. She said that the inputs given will strengthen the document further.

Dr. Madhur Gupta, Technical Officer-Pharmaceuticals, WHO Country Office for India, stated that it was a fruitful day with a lot of discussions over the various sections of the guidelines and a huge number of inputs have been received from various stakeholders.

Finally, **Dr. Roli Mathur** thanked everyone for the fruitful conclusion of the national consultation meeting. She informed that all the suggestions would be taken to the Advisory Group for their consideration before finalization of revised ICMR Ethical Guidelines.

Meeting Agenda Regional Consultation

ICMR –WHO Regional Consultation
"National Ethical Guidelines for Biomedical and Health Research involving Human Participants, 2016"

Date: 4 Oct 2016 Time: 9 AM- 5.30 PM

Venue: Conference Hall (GF), National Centre for Disease Informatics and Research, Indian Council of Medical Research, Nirmal Bhawan, Poojanhalli Road, Off NH-7, Adjacent to Trumpet Flyover of BIAL, Kannamangala Post, Bangalore- 562110

9.00 - 9.30 AM	**Registration**	
9.30 -10.00 AM Opening Session	• Welcome by Director NCDIR: Dr. Prashant Mathur • Remarks by Chairperson: Dr Vasantha Muthuswamy • WHO Perspective: Dr Madhur Gupta, WHO India Country Office • Vote of Thanks: Dr. Roli Mathur	
10-11.00 AM Panel Discussion I	General Ethical Issues Informed Consent Process, Vulnerability	Dr. K K Talwar (Chairperson) Dr. Joseph Thomas (Moderator) Dr. Olinda Timms Dr. Pratima Murthy Dr. Meenakshi Bhat Dr. Tarun Bhatnagar
11-12.00 noon Panel Discussion II	Ethical Review Procedures	Dr. Alok Srivastava (Chairperson) Dr. Vijay Prakash Mathur (Moderator) Dr. George Thomas Dr Madhur Gupta Prof.(Dr) Bishnu Ram Das Dr. S.V. Joga Rao
12-1.00 PM Panel Discussion III	Epidemiological, Public Health, Socio-Behavioral Sciences, Humanitarian Emergencies / Disasters Research	Dr. NK Arora (Chairperson) Dr. Mala Ramanathan (Moderator) Dr. M. K. Sudarshan Mr H. L. Gundu Rao Dr Dorothy Lall Dr Ragini Kulkarni
1- 2.00 PM	**LUNCH**	
2-3.00 PM Panel Discussion IV	Clinical trials of drugs and other interventions and New Technologies	Dr. G K Rath (Chairperson) Dr. Santanu Tripathi (Moderator) Dr. Sanish Davis Dr. P. Jambulingam Dr. Mudgal Kothekar Dr. P. Satish Chandra
3-4.00 PM Panel Discussion V	Human Genetics Testing and Research, Biological materials, Biobanking and Datasets	Dr. H Sharat Chandra (Chairperson) Dr. Manjulika Vaz (Moderator) Dr. Janet Parameshwar Dr. Raghu Padinjat Dr Jayarama S Kadandale
4- 4.30 PM Panel Discussion VI	International Collaboration, Responsible Conduct of Research	Dr. R C Mahajan (Chairperson) Dr. Siddhartha Laskar (Moderator) Dr Pradeep Menon Dr R.R. Gangakhedkar Dr. G D Ravindran
4.30 -5.00 PM	**Discussion and Final Recommendations**	
5- 5.30 PM	**Tea and Closure**	

Meeting Agenda National Consultation

ICMR –WHO National Consultation
"National Ethical Guidelines for Biomedical and Health Research involving Human Participants"

Date: 14th December, 2016 Time: 9 AM- 5.00 PM

Venue: Conference Hall (Second Floor), Indian Council of Medical Research, Ansari Nagar, New Delhi – 110029

9.00 - 9.15 AM	**Registration**	
9.15 -10.00 AM Opening Session	• **Welcome by Co - Chairperson (Advisory Group): Dr. S. D. Seth** • **Remarks by Advisory Group Members: Dr. Nandini K Kumar, Dr. N. K. Arora, Dr. Urmila Thatte and Dr. Vijay Kumar** • **Remarks by WHO Representative: Dr. Henk Bekedam** • **Remarks by DG, ICMR: Dr. Soumya Swaminathan** • **Vote of Thanks: Dr. Roli Mathur**	
10-11.00 AM Panel Discussion I	General Ethical Issues Informed Consent Process, Vulnerability	Chairperson: Dr. Gagandeep Kang Panelist 1: Dr. Amar Jesani Panelist 2: Dr. V. G. Somani Panelist 3: Dr. Nalin Mehta
11-12.00 noon Panel Discussion II	Ethical Review Procedures	Chairperson: Dr. Kusum Verma Panelist 1: Dr. Madhur Gupta Panelist 2: Dr. Sita Naik Panelist 3: Dr. Prabha Desikan Panelist 4: Ms. Annam Visala
12-1.00 PM Panel Discussion III	Public Health Research, Socio-Behavioral Sciences, Humanitarian Emergencies/ Disasters Research	Chairperson: Dr. Sanjay Mehendale Panelist 1: Dr. Amita Singh Panelist 2: Dr. Ravi Verma Panelist 3: Dr. Sanghamitra Pati
1- 2.00 PM	**LUNCH**	
2-3.00 PM Panel Discussion IV	Clinical trials of drugs and other interventions	Chairperson: Dr. Y. K. Gupta Panelist 1: Dr. V. G. Somani Panelist 2: Dr. Arun Bhatt Panelist 3: Dr. Upendra Kaul
3-4.00 PM Panel Discussion V	Human Genetics Testing and Research, Biological materials, Biobanking and Datasets	Chairperson: Dr. N. K. Mehra Panelist 1: Dr. Poonam Salotra Panelist 2: Mr. Prasanna Kumar B Shirol Panelist 3: Dr. Ratna Puri
4- 4.30 PM Panel Discussion VI	International Collaboration, Responsible Conduct of Research	Chairperson: Dr. Indira Nath Panelist 1: Dr. T. S. Rao Panelist 2: Dr. Anant Bhan Panelist 3: Dr. Nithya Gogtay
4.30 - 5.00 PM Concluding Remarks	• Dr. Madhur Gupta (Technical Officer, WHO Country Office for India) • Dr. G. N. Singh (Drugs Controller General of India) • Dr. P. N. Tandon (Chairperson, Central Ethics Committee for Human Research)	

List of Participants Regional Consultation, NCDIR, Bangalore

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Dr. B Ravichandran Scientist D & Officer-in-Charge Regional Occupational Health Center (S), Nirmal Bhavan, ICMR Complex, Poojanahalli Road Devanahalli Taluk, NH44, Kannamangala, Bangalore – 562110	**Prof. (Dr) Bishnu Ram Das** Professor, & Head Deptt of Community Medicine, Assam Medical College Barbari, Dibrugarh, Assam, PIN - 786 002	**Dr. Dorothy Lall** Member-secretary IPH Ethics Committee Institute of Public Health, No 250, 2nd 'C' Cross, 2nd 'C' Main, Girinagar 1st Phase, Bangalore – 560085
Dr. Debjit Chakraborty Scientist-B NCDIR, Nirmal Bhawan - ICMR Complex (II Floor), Poojanahalli Road, Kannamangala Post, Bangalore – 562 110	**Mrs. F S Roselind** Scientist-D NCDIR, Nirmal Bhawan - ICMR Complex (II Floor), Poojanahalli Road, Kannamangala Post, Bangalore – 562 110	**Dr. G D Ravindran** Professor& Head General Medicine, St John's Medical College, Sarjapur Road, Bangalore – 560 034
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