

ESIC Medical College & PGIMSR, KK Nagar, Chennai
Medical Education Unit
Ethical Practice of Health Research – Workshop

Date: 15 and 16 June 2017

Time: 9.30 AM to 4.00 PM

Venue: Conference Hall, ESIC Medical College & PGIMSR, KK Nagar, Chennai 600078

Introduction:

Health research is an essential endeavour that all doctors engage in right from their post-graduation days in order to contribute to new knowledge in medicine. With the emphasis of the Medical Council of India on research and research publication, all medical teachers are required to engage in active research and publications in order to progress in the academic ladder. At the ESIC Medical College & PGIMSR, KK Nagar, on an average about 20-30 research projects are ongoing at any given point of time. These include undergraduate, postgraduate and faculty research. Most of these research are non-funded, investigator initiated projects, however recently some externally funded research projects are also being undertaken in the institution. In the future the institution is more likely to expand in scope, into a research centre of excellence in the field of medical and health care research.

One of the essential requirements of conducting health care research, is a sound understanding and engagement with principles of ethical practice. All investigators need to undergo a rigorous training on the various ethical principles of conducting human participants research and should apply these principles in their own research projects. This workshop is an initiative to train the researchers in this institution on ethics of health research.

Objectives:

At the end of the workshop the participants will be able:

1. To list the key ethical principles that govern health care research
2. To identify the ethical considerations in specific health research scenarios
3. To prepare a research protocol keeping ethical considerations in mind

About the Workshop:

The workshop was conducted over a period of 2 days on 15 and 16 June 2017. There were a total of 15 sessions, with 10 lectures and 5 group discussions. The lectures were also delivered with generous use of practical examples and participant interactions were encouraged during the presentations. The group discussions were each for a duration of 20 minutes, with 10 minutes for plenary group discussions and debriefing. The detailed program schedule is enclosed.

Who participated

A total of 31 participants enrolled for the workshop, out of which 30 completely attended all the sessions. They were divided into 5 groups of six participants each. The detailed list of participants and their specializations is enclosed.

Program Schedule: 15 June 2017

Time	Topic	Specific Content	Facilitator
9.30 to 10.30 AM	Introduction to research ethics	Medical research vs. practice History of research ethics Declaration of Helsinki ICMR guidelines	Dr. Varalakshmi
10.30 – 11.00 AM	Inaugural Function		
11.00 – 11.15 AM	Coffee Break		
11.15 – 11.45 AM	Social value & Scientific Validity of Research	When is research socially valuable? What is the role of scientific validity? How is this ensured?	Dr. Vijayaprasad
11.45 – 12.15 PM	Group activity	Discussion in small groups on social value and scientific validity of research	Dr. Vijayaprasad
12.15 – 1.00 PM	Risks and Benefits of Research	How is risk benefit analysis performed? Practical examples	Dr. Varalakshmi
1.00 – 2.00 PM	Lunch Break		
2.00 – 2.30 PM	Group activity	Risk benefit analysis in the progressive case study	Dr. Varalakshmi
2.30 – 3.00 PM	Standards of Care	What are standards of care? De-jure and De-facto standards of care.	Dr. Vijayaprasad
3.00 – 3.15 PM	Coffee Break		
3.15 – 4.00 PM	Group activity	Standards of care consideration in the progressive case study	Dr. Vijayaprasad

Program Schedule: 16 June 2017

Time	Topic	Specific Content	Facilitator
9.30 to 10.30 AM	Respecting participant autonomy – Informed Consent	Principle of autonomy What is informed consent? Components of informed consent	Dr. Varalakshmi
10.30 – 11.00 AM	Group Activity	Autonomy and informed consent in progressive case study	Dr. Varalakshmi
11.00 – 11.15 AM	Coffee Break		
11.15 – 11.45 PM	Respect for participants – Privacy and Confidentiality	What is privacy and what is confidentiality? How are these ensured in research? Why should they be ensured?	Dr. Vijayaprasad
11.45 – 12.15 PM	Group Activity	Privacy and confidentiality concerns in the progressive case study	Dr. Vijayaprasad
12.15 – 1.00 PM	Justice considerations in health research	Justice as an animating principle	Dr. Vijayaprasad
1.00 – 2.00 PM	Lunch Break		
2.00 – 2.30 PM	Community Engagement	What is community engagement? Why is it important?	Dr. Vijayaprasad
2.30 – 3.15 PM	Research governance and Institutional Ethics Committee	Composition and functioning of an ethical committee	Dr. Varalakshmi
3.15 – 3.30 PM	Coffee Break		
3.30 – 4.00 PM	Research Integrity and publication ethics	Authorship, contributorship, plagiarism, falsification, fabrication	Dr. Vijayaparasad
4.00 – 4.15 PM	Concluding remarks and closing of workshop		

List of Participants:

S. No	Name	Designation	Department
1.	Dr. K. Uma Maheswari	Associate Prof	Physiology
2.	Dr. G. Sugapriya	Asst. Prof	Physiology
3.	Dr. V. Madhubala	Associate Prof	Biochemistry
4.	Dr. Veerendra Kumar Arumalla	Asst. Prof	Biochemistry
5.	Dr. K. Meenakshisundaram	Associate Prof	Pathology
6.	Dr. S. Shanmugapriya	Associate Prof	Pathology
7.	Dr. S. Seethalakshmi	Professor & Head	Pharmacology
8.	Dr. A. E. Vijaya Kumar	Asst. Prof	Pharmacology
9.	Dr. V. Sangamithra	Professor & Head	Microbiology
10.	Dr. Manisha S Mane	Associate Prof	Microbiology
11.	Dr. Suma Elangovan	Associate Prof	Ophthalmology
12.	Dr. G. Senthamarai	Senior Resident	Ophthalmology
13.	Dr. Anuradha R	Asst. Prof	Community Medicine
14.	Dr. A. R. Malathy	Professor & Head	General Medicine
15.	Dr. Senthilnathan	Asst. Prof	General Medicine
16.	Dr. Uday Shamrao Kumbhar	Professor	General Surgery
17.	Dr. Bhanumati Giridharan	Associate Prof	General Surgery
18.	Dr. Jayanthi Mohan	Professor & Head	Obstetrics & Gynaecology
19.	Dr. Gayathri S. R	Asst. Prof	Obstetrics & Gynaecology
20.	Dr. Ilango Ganesan	Associate Prof	Anaesthesia
21.	Dr. K. Radhika	Associate Prof	Anaesthesia
22.	Dr. Sathish Kumar	Asst. Prof	Paediatrics
23.	Dr. Subhashini M	Asst. Prof	Dermatology
24.	Dr. Tharikeswari T	Senior Resident	Radiology
25.	Dr. Vijayan B.	Asst. Prof	Orthopaedics
26.	Dr. G. Sakthiram	Junior Resident	Medicine
27.	Dr. K. Vijaya Durairaj	Junior Resident	Medicine

28.	Dr. Andrea Josephine R	Junior Resident	Medicine
29.	Dr. Kanika Gupta	Asst. Prof.	Radiology
30.	Dr. T. Rajeswari	Asst. Prof.	Pathology
31.	Dr. Sebasan	Asst. Prof.	General Medicine

Brief Profile of Facilitators:

Dr. Varalakshmi Elango MD

She graduated from Madras Medical College with MBBS in 1987 and with MD in Microbiology in 1992. She did her diploma in Medical Virology from the National Institute of Virology, Pune in 1998 and served for several years at the King Institute of Preventive Medicine (KIPM) in the department of medical virology. She has worked in several international projects on National Polio, Measles and Influenza Laboratories. Currently she is a freelance consultant, working with the World Health Organization (WHO), Drugs for Neglected Diseases Initiative (DNDi), and the Special Programme for Research and Training in Tropical Diseases (WHO/TDR). She has worked with the Global Health Ethics Unit of the WHO as well as the Good Laboratory Practices and Good Health Research Practices trainer for the WHO/TDR. She is currently the coordinator of all the regional training centres of WHO/TDR around the world. She serves in the Ethics Committee of the School of Public Health, SRM University. She is a member of the core group developing an online course for ethics committee members on research ethics, an initiative of the National Institute of Epidemiology and ICMR in collaboration with the WHO.

Dr. Vijayaprasad G. MD, PhD

He obtained his Bachelor of Medicine and Bachelor of Surgery (MBBS, 2002) from the Madras Medical College, Chennai and Doctor of Medicine in Community Medicine (MD, 2010) from the Christian Medical College, Vellore. Following this he worked at the Rural Women's Social Education Center, a rights based women's organization in Kancheepuram, providing community based health care services in rural areas. He pursued his doctoral research in Public Health at the SRM University, Kattankulathur, Kancheepuram District with an INSPIRE Fellowship from the Department of Science and Technology, Government of India. His area of work for the PhD was "trust in the doctor-patient relationship". After obtaining his PhD degree in Nov 2015, he is currently working as Assistant Professor at the Department of Community Medicine, ESIC Medical College and PGIMS, KK Nagar. His areas of interest include non-communicable diseases epidemiology, health communication, doctor-patient relationships, medical and public health ethics. He serves as working editor for the prestigious Indian Journal of Medical Ethics since 2014. He also consults for the World Health Organization for developing ethical guidelines for public health surveillance and developing curriculum for training in ethics of implementation research.

Proceedings of the Workshop:

Day 1 – 15.06.2017

Session 1: Introduction to Research Ethics – Dr. Varalakshmi Elango

In this session the participants were introduced to the distinction between clinical practice and clinical research. They were introduced to the four broad tenets of ethics of medical research, namely, autonomy, beneficence, non maleficence and justice. They were also introduced to the history of evolution of research ethics starting from the Nuremberg trials following the World War II. The facilitator also introduced the various guidelines of research ethics namely, the Declaration of Helsinki, CIOMS guidelines, ICH-GCP guidelines as well as the ICMR guidelines for biomedical research on human participants.

Inaugural Function

Following the introductory session, there was an official inaugural function.



Inaugural Function graced by the Dean, Vice Principle, Deputy Registrar, Coordinator of the Medical Education Unit and the Lead facilitator of the workshop

The coordinator of the medical education unit, Dr. Sowmya Sampath welcomed the gathering and introduced the importance of the workshop. This was followed by felicitation of the meeting by the Vice Principal, Dr. Seethalakshmi. Following this, the deputy Registrar Dr. Usha Kothandaraman wished the program the best. This was followed by a brief speech by Dr. Varalakshmi Elango, lead facilitator of the workshop, who expressed her interest in furthering the agenda of research ethics capacity building in the institution. The Dean, Dr. Srikumari Damodaram, delivered the inaugural address highlighting the importance of research ethics.

Session 2: Social Value and Scientific Validity of Research – Dr. Vijayaprasad

Following the inaugural, the second session was one on social value and scientific validity of research. The facilitator highlighted that social value of research is largely dependent on the ability to translate new knowledge gained by the research into something of health benefit to the community. It was also mentioned that scientific validity is the fundamental basis of ethical research. Poor scientific validity negates all other ethical considerations.

Group Discussion 1: Social Value and Scientific Validity of Research

The participants were divided into groups and discussed the various aspects of social value and scientific validity of research from a case study developed for the sake of this workshop. This case study takes the example of a research study and introduced progressively the various ethical consideration for discussion after each session.



Group discussions on the case study

Session 3 – Risks and Benefits of Research – Dr. Varalakshmi

Following the groups discussion on social value and scientific validity, Dr. Varalakshmi spoke on risk benefit analysis in health research. She highlighted the difference between risk and harm with practical examples. She also mentioned that harms in health research are not limited to physical harms, and they could be psychological, social and emotional harms too. Therefore a thorough considerations of risks, harms and benefits is essential.

Group Discussion 2 – Risks and Benefits of Health Research

The participants discussed the various aspects of risks and benefits in the case study. They discussed in the plenary about the various identified risks. They also discussed the balance between the risks and benefits. Finally, they highlighted the potential mitigation methods.

Session 4 – Standards of Care in Health Research – Dr. Vijayaprasad

This was followed by a presentation on standards of care in health research. In this session the facilitator highlighted that there could be universal best available standards of care, locally best available standards of care, less than best available standards of care or no care for the comparison group. The presentation covered various arguments for and against universal best available standards of care as well as less than best standard of care. The implications of such standards of care issues in international health research was illustrated with various examples.

Group Discussions 3 – Standards of Care

In the group discussion, there were rich discussions and arguments for and against various standards of care in the case study. The discussions lead to a comprehensive understanding of various arguments for and against a universal best available standard of care.

This group discussion marked the closing of the first day of the workshop.

Day 2 – 16.06.2017

Recall of previous day's learnings:

Four participants came forward and summarized six key messages that were learnt on the previous day in the workshop in the four sessions. The session was facilitated by Dr. Varalakshmi and the learning points were recalled and summarized.

Session 5 – Respecting participant autonomy – Informed Consent – Dr. Varalakshmi

In this session the facilitator highlighted the concept of autonomy. She further used rich illustrations and examples to highlight the various components of the informed consent document, the process of informed consent and the various issues in obtaining informed consent. She also highlighted the use of legally acceptable representatives in cases of participants who do not have the capacity to consent. The issue of using eye witnesses to the informed consent process were also illustrated with examples.

Session 6 – Respect for participants – Privacy and Confidentiality – Dr. Vijayaprasad

In this session the concepts of privacy and confidentiality were described and discussed in detail with adequate examples. The facilitator also highlighted the importance of protecting the privacy and confidentiality of research participants. It was also further highlighted that specific affirmative actions need to be taken to protect the privacy and confidentiality as these are essential components of personhood of a research participant.

Group Discussion 4 – Autonomy, Privacy and Confidentiality

This was a rich and productive group discussion which lasted almost an hour. In this session, the participants reflected on informed consent process in the case study. They also highlighted the various nuances of compromised autonomy in terms of coercion, undue influence etc. The issue of privacy and confidentiality was also richly discussed based on the case study.

Session 7 – Justice Considerations in Health Research – Dr. Vijayaprasad

In this session the focus was on the concept of justice. The various dimensions of justice namely, distributive justice, procedural justice and compensatory justice were discussed. In distributive justice it was mentioned that not only should there be a balance between benefits and burdens, the benefits and burdens should also be equitably distributed. It was also highlighted that justice consideration can be based on egalitarianism, equity, welfare or impartiality. Various examples of justice considerations in health research were provided to illustrate the concepts.

Group Discussion 5 – Justice Considerations in Health Research

The justice considerations in health research in the progressive case study were discussed in the plenary group discussion. The various nuances of participant selection, research on vulnerable participants and justice considerations were discussed richly.

Session 8 – Community Engagement in Health Research – Dr. Vijayaprasad

The facilitator made a brief presentation on what is community engagement. He highlighted that by engaging with communities for research, there is an overall benefit in terms of improved participation, better communication with the participants, better quality of informed consent and more trust in research. The facilitator also pointed out that community engagement is an ethical imperative in health research.

Session 9 – Research Governance – Dr. Varalakshmi

In this session Dr. Varalakshmi highlighted the establishment, composition and functions of an ethics committee. She used several examples and case scenarios to highlight the various activities of an ethics committee.

Session 10 – Research Integrity and Publication Ethics – Dr. Vijayaprasad

In this session the facilitator highlighted that medical research is completely based on the level of integrity exhibited by the researcher. The various aspects of publication ethics such as authorship, redundant publications, plagiarism, falsification or fabrication of data and conflicts of interest in research publication were all discussed in detail.

Feedback from participants:

The participants were requested to give feedback on all the sessions immediately following the sessions. The feedback was obtained on a 5-point scale – 5 indicating the best and 1 indicating the worst performance. The domains on which the feedback were obtained included:

Clarity of objectives, plan and layout of the session, delivery of the session by facilitator, ease of understanding the content, quality of examples used, acquiring new knowledge and skills, quality of the PowerPoint presentation, scope for participant interactions, quality of the case study and discussion and time allotted for the session.

The following were the average rating given to each session by the participants:

S.No	Session Title	Number of participant who gave feedback	Average Score (50)
1	Introduction to Research Ethics	29	46.3
2	Social Value and Scientific Validity of Health Research	26	45.6
3	Risks and Benefits of Health Research	27	46.4
4	Standards of Care in Health Research	29	45.7
5	Autonomy and Informed Consent	28	46.5
6	Privacy and Confidentiality	29	46.6
7	Justice considerations in Health Research	28	45.1
8	Community Engagement in Health Research	16	44.3
9	Research Governance and IRB	18	46.5
10	Research Integrity and Publication Ethics	11	47.2

According to the feedback received, it was seen that research integrity & publication ethics and the session on privacy and confidentiality were rated the top two sessions and the session on

community engagement in health research was rated the lowest. However, even the lowest rating was about 44.3 out of a maximum score of 50.

Valedictory Function:

The session was formally closed with the distribution of certificates to the participants. The lead facilitator Dr. Varalakshmi Elango awarded the certificates to those who successfully completed the workshop.



Distribution of certificates to the participants during the valedictory ceremony

Proposed Follow up Action:

Based on participant feedback and request, a follow up workshop on protocol development for health research will be planned.

In order to evaluate the effectiveness of this workshop two long term follow up will be conducted:

1. Assessment of ethical commentary on the research proposals of the workshop participants will be performed