

Report on the Intensive short training course in Ethical issues in Biomedical Research conducted from 27th May to 31st May 2013

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| <p>1. Name of the Event : Intensive Short Training Course on Ethical Issues in Biomedical Research</p> | <p>Date: 27th May to 31st May 2013 Time : 8.30a.m. to 5.00p.m. x 5 days Total Hours: More than 35 hours</p> |
| <p>3. Organising Secretary/Co-ordinator: Dr.Vina Vaswani, Director – Centre for Ethics</p> | <p>4. Organising dept. & College : Centre for Ethics, Department of Forensic Medicine, Yenepoya Medical College,</p> |
| <p>5. (1) Total number of candidates registered : 34 (ii) Total number of candidates attended : 30</p> | <p>(iii) Number of Internal participants : 17 (iv)Number of External Participants :13</p> |
| <p>6. List of Resource persons: 7 (For profile - Refer annexure 1)</p> <ul style="list-style-type: none"> a) Dr.Richard Cash: Senior Lecturer on Global Health, Department of Global Health and Population, Harvard School of Public Health, Harvard University, USA b) Dr.Amar Jesani: Honorary Trustee of Anusandhan Trust, Mumbai and Founder IJME c) Dr.Arun Bhatt: President, Clininvent Research Pvt.Ltd. d) Dr.Mala Ramanathan: Additional Professor, Achuta Menon Centre for Health Science Studies and Member, Institutional Ethics Committee, Sri Chitra Tirunal Institute of Medical Science and Technology, Trivandrum. e) Dr.Vina Vaswani: Head –Department of Forensic Medicine and Toxicology, Yenepoya Medical College and Director, Center for Ethics, Yenepoya University. f) Dr.Nandini K Kumar: Former Deputy Director General Senior Grade of the Indian Council of Medical Research (ICMR), New Delhi. g) Dr.Corinna Porteri: Head Bioethics Unit, IRCCS Saint John of God, Fatebenefratelli, Brescia, Italy. | |

Details of the sessions: The learning objectives for each session were spelt out. The day began with a quick recap of the earlier day and ended with feedback session. During the first day a pre test questionnaire was administered to all the participants which was anonymized and on the last day Post test evaluation was also conducted. Besides pre and post test evaluation, sessions feedback and program evaluation was done. The feedback from the resource persons was also collected.

Day to day time table and session objectives (**Refer annexure no.2**)

Brief report on the event

Background and Justification:

Today, majority of the world's clinical are conducted in Asian countries. India ranks as a top country for providing a huge market of participants and at costs significantly lesser. Commensurate with this burst in clinical trials, ethics committees have also sprouted across the country. The problem is that majority of the members who sit in these ethics committees to sanction ethical clearance to clinical trials are not trained in the process of ethical clearances and the fixing of compensation, in case of harm to participants. Hence Centre for Ethics, Yenepoya University conceived this event with the vision of training researchers as well as ethics committee members in the skills required to carry out research in ethical manner and to learn how to perform better on ethics committees. For the past two years Yenepoya University has been conducting this annual training program with National and International faculty.

The main purpose of organization this course was to empower participants who are presently engaged in research or are serving on institutional ethics committees; or are likely to do so in the coming years-empower them to recognize and deal with various ethical issues arising out of research in India, and are structured using the current guidelines of the Indian Council of Medical Research, the Schedule Y of the Drugs and Cosmetics Act, the ICH-GCP and other relevant national and international bodies.

Planning:

The planning was started 7-8 months in advance, with confirmation of the resource persons' availability since they are all international renowned faculty. Brochures were printed, after approval from the University and widely disseminated including the fourth National Bio ethics conference held in Hyderabad, different health care institutions in Karnataka, Medical colleges and independent ethics committees. Pre-test and post-test

questionnaires were circulated among the resource persons for validating. Reading material was collected from the resource persons, along with their travel itinerary. All the presentations and reading material were combined and distributed to the participants, via email and CDs. Accreditation was sought from Karnataka Medical Council and 10 credits were awarded to the event. We applied to Indian Council for Medical Research for funding and they were pleased to partially sponsor the event.

Filled registration forms were received and profile of participants was built on Microsoft Excel sheet. Catering and Inaugural program arrangements (including press release, banners and stage) were all completed. Accommodation (hostel-type) was arranged for out-station members in the international hostel.

The inaugural programme was conducted on 27th May 2013 by planting of the saplings in the University campus by Dr.Nandini Kumar and Dr.Corinna Porteri, and a brief programme of one hour in the Indoor Auditorium of the University. The Vice Chancellor of the University presided over the function.

(Invitation enclosed- Annexure no.3)

During the registration all participants were provided with a jute shoulder bag, file, writing pad, pen and other handouts.

Advantage to the University:

Direct advantage:

1. 17 faculty members received intensive training in the workshop on Ethical issues in Biomedical Research. This will over the years build a pool of faculty trained and exposed to Research Ethics. These faculty members can:-
 - a) Serve on ethics committees in a more meaningful manner and enhance the functioning of Yenepoya University Ethics Committee.
 - b) Perform research using protocols designed to conform to the highest ethical standards as laid down by ICMR and Drugs and Cosmetics Act.
2. The Director General of Indian Council of Medical Research (ICMR), New Delhi, has granted a financial assistance of Rs.50,000/- for organizing the Research Ethics Workshop.
3. The Karnataka Medical Council Trust @, Bangalore has awarded ten hours of accreditation for the five days program and one hour per day accreditation to faculty.

Indirect Benefits:

Out of the 30 participants registered, 13 were from outside Yenepoya University and of this 13, 7 were from outside Mangalore. By word of mouth these participants will attract more participants next year. Additionally many of these participants already are serving as Ethics Committee members or are likely to do so or are active researchers in their own right. By conducting this workshop the Centre for Ethics is enhancing the upgrading of quality of research and ethical reviews across the country.

Patient benefits:

When the research or the trial is significant and ethical then it goes for publication in Peer review journals then it can form the basis for evidence. A good trial with ethics helps the patient/participant. It will also have confidence from the people when research is for the benefit of the people.

Any other information:

30 participants completed their training. The analysis showed a significant improvement. Those who had not been exposed to ethical issues in clinical trials before, were able to see first-hand how clinical trials are analysed by ethics committees, through the mock clinical trial presentation. Five members who were already in the Ethics Committee felt that this training helped them to understand the perspectives even better.

17 faculty members of Yenepoya University attended the workshop. All expressed satisfaction on the content, quality and choice of resource persons. All expressed that more of such programs should be conducted.

All participants enjoyed the viewing of movies that brought out the ethical issues in biomedical research and enjoyed the post-movie deliberations on these issues.

The course concluded by distribution of the certificates from the University, a C.D. containing all the presentations from the resource persons and also a print of the group photograph.

Future plans:

We intend to have yearly program for training ethics committee members as well as researchers. One of the valuable lessons that participants learnt was that researchers who always thought of Ethics Committee as obstacles to their projects now expressed belief in the process that Ethics Committee needs to look into the minute details and they felt justified that ethical principles must be applied while dealing with the study of human subjects.

The Centre for Ethics, Yenepoya University is mooted a proposal that all intra-mural researchers and ethics committee members undergo this training before they do their respective roles. This will ensure better and more ethical research proposals, which will enhance the image of the University and also increase the efficiency of the ethics committee thereby earning the trust of the community and society.

Dr.Vina Vaswani
Director –Centre for Ethics