National Institute of Epidemiology (NIE)

Minutes of the Institutional Ethics Committee (IEC) Meeting

On 14th Dec. and 18th Dec. 2002

Venue: National Institute of Epidemiology, ICMR, Chennai

Members Present:
1. Dr. R. Prabhakar
2. Shri. G. Srinivasan
3. Dr. P. Manorama (could not attend on 18th Dec. 2002)
4. Father. Desmond Daniels
5. Shri. S. Jayaraman
6. Dr. Thilakavathi Subramanian - Member Secretary

Special Invitee
7. Shri. Sriram Panchu

NIE Officers: Dr. M. D. Gupte, Dr. B. Nagaraju, Dr. B.N. Moorthy, Dr. Sreevatsa, Dr. T. Venkata Rao, Dr. R. L. J. Britto, Dr. Vidya Ramachandran and Dr. P. Manickam

The following members could not attend the meetings.
1. Dr. Shuba Kumar
2. Dr. M. Suresh Kumar

On behalf of NIE Dr. M. D. Gupte extended welcome to all the members of the Committee. He informed them about the sad demise of Justice Shri. N. Krishnaswamy Reddy, Chairman, Ethics Committee. He requested Dr. R. Prabhakar to accept the Chairmanship for the present meeting and conduct the proceedings. Dr. Prabhakar accepted the request.

Condolence meeting:

A condolence meeting was held as a part of the proceedings. In this meeting the members narrated their experiences with the former Chairman and remembered his
contributions in different fields. Justice Reddy was described as a multifarious personality in the public life.

Dr. Prabhakar said that he had learnt a lot from Justice Reddy in dealing with ethical issues in various research activities. Dr. Prabhakar remembered his humane approach and his ability to identify himself with the common man.

Dr. Gupte narrated about Justice Reddy's commitment and affinity with NIE as the Chairman of the IEC. He mentioned that Justice Reddy used to visit Leprosy vaccine Trial area with him for continuing ethical review of the study. Thus the ethics committee under his Chairmanship became an exemplary one in the country. Dr. Gupte informed the IEC that Justice Reddy was very keen that the meeting of the IEC should be conducted, even though he might not be able to participate in the same.

Mr. Srinivasan said that he visited Justice Reddy along with Dr. Gupte in 1990 to request him to be the Chairman for the Ethics Committee. He further praised him as an educationist and recalled his contributions to the Vivekananda Educational Society for a long period.

Mr. S. Jayaraman mentioned that Justice Reddy was down to earth practical; praised him for his excellent judgments with human approach.

Father Daniels praised the multifaceted personality of Justice and the wonderful movements he had created.

Mr. Sriram Panchu said that Justice Reddy was an outstanding judge and was responsible for the establishment of the Legal aid Cell for the poor.

Dr. Thilakavathi narrated about his commitments to the community.

IEC passed a resolution expressing their gratitude to Justice Reddy for his unique contributions to the development of a tradition of good ethics committees in India.
As a mark of respect to the departed soul, the members of the committee and NIE Officers stood for a minute in silence.

Resignation of Mr. D. K. Sampath:

Dr. Thilakavathi informed the committee about the resignation letter from Shri. D. K. Sampth from the membership of our IEC, on account of the difficulties he was facing with his eyesight. His resignation was accepted. Shri. S. Jayaraman, Advocate, Madras High Court was requested to be the member of this Ethics Committee and he kindly accepted to be the member of the IEC.

Dr. Prabhakar asked the secretary of the IEC to communicate appreciation by the IEC to Shri. D. K. Sampath for his contributions all these years as a member of the IEC and particularly about his deep thinking and understanding of the problems with respect to consent in vaccine trials.

IEC review of various proposals

IEC considered various proposals in two sittings, on 14th and 18th Dec. 2002.

Various studies, earlier approved by the institute's Scientific Advisory Committee (SAC), were presented to the IEC.

1. Formative research leading to the development of an intervention to reduce the risk of sexual transmission of HIV and STIs among Injection Drug users and their sexual partners (Dr. P. Manickam)

This study is proposed in collaboration with SAHAI TRUST (NGO), Chennai. The IEC member Father. Desmond Daniels was not involved in the decision-making of the approval as he was from SAHAI TRUST.

The proposal was approved.

- The IEC suggested that the consent form should be explicit covering the confidentiality of all data and, in case of illiterates, to get the signature of the person who would read the consent form to the respondent.
• IEC was informed that the treatment for the HIV positives will be taken care of as per the NACO guidelines.

2. Epidemiology of STIs in a Rural Community adjacent to truck stops (Dr. Thilakavathi Subramanian)

The proposal was approved.

• The IEC suggested, to consider inclusion of Dhaba owners and truckers in the intervention part of the study and to provide counselling support during baseline survey.

• The IEC suggested to consider syndromic management of STIs. The IEC advised, to have separate code number for each respondent to maintain confidentiality.

3. Study on CVD Risk factors among Industrial population in Chennai (Dr. T. Venkata Rao)

This study is proposed in collaboration with Sundaram Medical Foundation, Chennai.

The proposal was approved.

• It was noted that TVS Groups in general and Brakes India in particular was considered for the study in view of the availability of quality data, health care facilities, good routine follow-up and willingness of the industrial group for taking up studies in this area. The IEC agreed that such a study could be taken up to gain experience under almost controlled conditions, since NIE was developing such studies for the first time.

• The IEC suggested that the proposal should include a section indicating that NIE would utilise the findings from the present study for future studies with respect to other industrial workers and general population.

4. Feasibility of Recruitment and Retention of a cohort of couples seeking treatment for STDs (Dr. Thilakavathi Subramanian)

This study is proposed in collaboration with University of California, Los Angeles (UCLA), to be conducted at Institute of Venereology, Govt. General Hospital, Chennai.

The proposal was approved.
The IEC suggested that a copy of the consent form to be given to the respondent and acknowledgement for the receipt of the same should be with the investigator.

It was suggested to limit the geographical area for the study by considering only Chennai based patients.

5. Development of Prevention Intervention for STD patients (Dr. Thilakavathi Subramanian)

This study is proposed in collaboration with University of California, Los Angeles (UCLA), to be conducted at Institute of Venereology, Govt. General Hospital, Chennai.

The proposal was approved.

The IEC suggested to get written consent from the Focus Group participants (STD patients).

6. Prevalence of neurological lesions in MB patients, 5 years or more after completion of WHO MB MDT regimen (Dr. B. Nagaraju)

The proposal was accepted.

The committee suggested to provide Health Education about the management of ulcer, community based physiotherapy and self care and, to have informed consent from each respondent.

7. Nutritional status and HIV infection among IDUs in Chennai – A cross sectional study (Dr. P. Manickam)

This study is proposed in collaboration with SAHAI TRUST (NGO), Chennai. The IEC member Father Desmond Daniels was not involved in the decision making of approval, as he was from SAHAI TRUST.

The proposal was approved.

8. Epidemiological profile of Acute Respiratory Infection among pre-school children in rural south India (Dr. R.L.J. Britto)

The proposal was approved.
9. Lot Quality assurance Survey for Monitoring Immunization Coverage in Tamil Nadu (Dr. B. N. Murthy)

The proposal was approved.

- The IEC observed, since NIE was involved in only designing the study, there were no real ethical issues for consideration.

10. Prevalence of Diabetes and impaired glucose tolerance in the urban adult population of Thakthing village council area, Aizawl, Mizoram, A pilot study: (Dr. Vidya Ramachandran)

This proposal was submitted by an FETP student of NIE from Mizoram Govt. to the IEC.

The Proposal was approved.

- The IEC suggested that treatment be provided to the detected diabetes patients who opt for treatment from the Govt. facilities and to provide counselling services for the respondents who dropout midway in the study.

11. Uniform Multi Drug Therapy regimen for all leprosy patients (Dr. M.D. Gupte).

The proposal was approved.

General Recommendation:

Dr. Gupte suggested that NIE could organise a symposium on ethical aspects for studies relating to HIV infection and AIDS. Mr. Sriram Panchu strongly supported this suggestion and wanted the scope of the symposium to be expanded beyond the NIE -IEC. IEC readily welcomed this recommendation.

Conclusion of the meeting:

Dr. Prabhakar appreciated the efforts of all the NIE officers and the Director for developing several important studies and for the frank discussions.

The meeting came to an end with a vote of thanks to the Chairman and members of the committee.