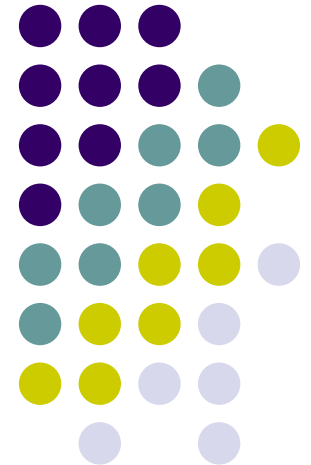


Ethical Review of Proposals in Resource Poor Settings

II National Bioethics Conference,
Bangalore
SCTIMST





Facilitators

- Dr.P.Sankara Sarma, Additional Professor, AMCHSS, SCTIMST
- Dr.Anoop Kumar Thekkuveetil, Scientist 'G', BMT, SCTIMST
- Dr.Girish Menon, Additional Professor, Dept of Neurosurgery, SCTIMST
- Dr.Mala Ramanathan, Additional Professor AMCHSS, SCTIMST

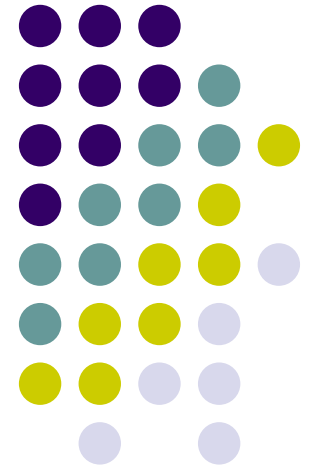


The Institution

- SCTIMST – three wings, the Biomedical Technology wing, the Hospital wing and the Health Sciences wing
- Diversity of research activities
- The need for quality reviews

Introduction

Mala Ramanathan
IEC and TAC –AMC member,
SCTIMST



The Institutional Ethics Committee



- A statutory body of the Institute, appointed by the Governing Body of the Institute
- Single committee to review all proposals from three wings
- Number of members: 12, 4 internal members and 8 external members
- Quorum requirements for decision: at least 4 members, of which at least 50% consists of external members

Objectives of the SCTIMST-IEC



- To protect the dignity, rights and well being of the potential research participants with emphasis on human rights
- To ensure that universal ethical values and international scientific standards are expressed in terms of local community values and customs and
- To assist in the development and education of a research community responsive to local health care requirements

Composition



- Required
 - 1. Chairperson , 2. Two Scientists (preferably one from Clinical Pharmacology and another from Public health), 3. One or Two Clinicians (preferably one from Medical and another from Surgical specialty), 4. One or two Biomedical Scientists / Engineers (involved in the development / evaluation of biomaterials and/or medical devices), 5. One Legal Expert (preferably a retired judge), 6. One Social Scientist /Social Worker, 7. One Philosopher or Ethicist, 8. One Lay Person from the community, 9. Member Secretary
- Reality
 - Multiple roles of persons – Ethicist and social scientist/researcher, Lay person who is social worker, Retired Judge from the High Court of Kerala as Chair and so on

Functioning



- Chaired by an external member
- Prior notified dates for meeting, second/third Saturday of the second, fifth, eighth and eleventh month
- Convener of the meeting – the member secretary, an internal member
- The Secretariat – responsible for facilitating the Member Secretary's role in terms of collecting proposals, preparing the agenda (list of proposals for discussion and other relevant matters) for the IEC Meeting, mailing documents and other communications to the IEC members, etc



Review process

- The Chair appoints primary and secondary reviewers for each agenda item
- All members are expected to review all the proposals, nevertheless
- Decision making is after review (usually primary and secondary reviewers are appointed) and discussion and usually by consensus. If consensus is not possible by voting

Additional Responsibilities of IEC members



- Maintain confidentiality
- Report Conflict of Interest, if any and recuse oneself
- Refrain from review process and decision making in case of C of I



Operational Problems

- Specific skills to complete expert technical review – not always present within IEC
- Presence of external members and their strength ensures transparency and fairness, but as they take on the role voluntarily, may find too taxing to take up more frequently
- Travel time and costs, the burden of the review process
- The difficulties of reviewing SAEs



Technical Solutions

- Separation of the technical review process through the three Technical Advisory Committees
- Setting up Sub-Committees for review of student proposals and expert reviews
- Developing processes for expedited review and waiver of review
- Requiring a local DSMB to be set up for each clinical trial

Logistic Solutions



- Reduction of costs by charging
- Reduction of mailing costs by using soft copies for some proposals



The Presentations from the group

- Discussion of the IEC functioning and costs – Member Secretary, SCTIMST, Dr. Anoop Kumar Thekkuveetil
- Discussion of the various sub-committees – Chair of the AMCHSS TAC, Dr. P. Sankara Sarma
- Discussion of the Technical Advisory Committee, Member Secretary, Hospital TAC, Dr. Girish Menon



The last presentation will be followed by group discussions based on case studies being distributed that highlight some of the problems that are resolved using the processes put in place at SCTIMST

Thank you