Enhanced Roles and Responsibilities of Ethics Committees

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OUTLINE

Ethics Committee
- Composition
- Roles and Responsibilities of Members
- Functioning (SOPs, checklist, types of review, monitoring)
- Decision Making
- Review Process
- Risk Benefit Assessment
- Communications (reporting, timelines, communications to PI, DCGI, Response to Subject)
Institutional Ethics Committee (IEC)

The purpose of an IEC is to review research and to ensure the rights and welfare of human subjects involved in research are adequately protected.
IEC in India

- Pink Book
- First ICMR ethical guidelines were prepared under Justice H.R Khanna in Feb 1980
  - establishment of ethics committees in all centres involved in clinical research
  - membership criteria and ethical standards for review
  - asserted that ethics committees "must be independent"
  - To empower them as regulators, made a commitment that all research projects should be approved by the ethics committee
Ethical Guidelines, 2000

- Revised ICMR ethical Guidelines were prepared by a committee under Justice MN Venkatachaliah in 2000.
- It is mandatory that all proposals on biomedical research involving human subjects should be cleared by an appropriately constituted Institutional Ethics Committee (IEC), to safeguard the welfare and the rights of the participants.
- The IEC are entrusted not only with the initial review of the proposed research protocols prior to initiation of the projects but also have a continuing responsibility of regular monitoring for the compliance.
Revised Guidelines, 2006

- Composition as Sch Y and as per Guidelines
- Terms of reference
- Training
- Review Procedures: Exemption, expedited, Full review
- Decision making
- Continuing review
- Monitoring
- Record Keeping
- Administration and management
Directly Regulated - Clinical Trials
Indirectly regulated - biomedical research

Role of Ethics Committees & Regulations

AIM

Ensure not only protection of research subjects, but also wide public acceptance / trust / confidence in biomedical research
RESPONSIBILITIES OF ETHICS COMMITTEES

1. To protect the dignity, rights, well-being of research participants.
2. To ensure universal ethical values are expressed in terms of local community values and customs.
3. To assist in development and education of research community responsive to local health care requirements.
4. To enforce all statutory/non-statutory provisions related to ethics in medical research – with sound judgment and meticulousness
5. To function as per laid down SOPs in an independent and transparent manner
6. To maintain records and archive the same
7. To remain abreast with emerging ethical issues due to advancements in science and technology
Institutional Ethics Committees- Elements

- Structure
- Function
- Competence
- Independence

(IEC, REC, IRB, ERC, EC etc)
ICMR Ethical Guidelines

- Chairperson
- One - two persons from basic medical science area
- One - two clinicians from various Institutes
- One legal expert or retired judge
- One social scientist/ representative of non-governmental voluntary agency
- One philosopher/ ethicist/ theologian
- One lay person from the community
- One member Secretary

Adequate representation of age and gender

Schedule Y (2005)

- One basic medical scientist (preferably one pharmacologist).
- One clinician
- One legal expert or retired judge
- One social scientist/ representative of non-governmental organisation/philosopher/ ethicist/ theologian or a similar person
- One lay person from the community
SPECIAL SITUATIONS FOR IECs
Roles of IEC Members
TERMS OF REFERENCE

- Appointment Procedures
- Term
- Remuneration
- CV & training Records
- Confidentiality Agreements
- Conflict of Interest Declarations
Basic Knowledge for IEC Members

- Background:
- Foundation Knowledge:
- Methodological issues:
- Conflicts of Interest
- Reviewing research proposals:
- Responsibilities
TRAINING
IEC Responsibilities

One time Initial Review & Approval
ELEMENTS OF REVIEW

- The primary task of the IRB is to review research proposals and their supporting documents with special attention to:
  - The scientific validity,
  - The suitability and feasibility of the study.
  - Informed consent
Scientific Design & Conduct of Research
Protection of Research Participants
# Standard Operating Procedures (SOPs)

## List of FERCAP SOPs

1. Writing, Reviewing, Distributing and Amending Standard Operating Procedures for Ethics Committees SOP/001/01.0
2. Preparation of Guidelines SOP/002/01.0
3. Constituting an IEC/IRB SOP/003/01.0
4. Conflict of Interest Agreements SOP/004/01.0
5. Training Personnel and IEC/IRB Members SOP/005/01.0
6. Selection of Independent Consultants SOP/006/01.0
7. Management of Protocol Submissions SOP/007/01.0
8. Use of Study Assessment Forms SOP/008/01.0
9. Expedited Review SOP/009/01.0
10. Initial Review of Submitted Protocols SOP/010/01.0
11. Review of New Medical Device Studies SOP/011/01.0
12. Review of Resubmitted Protocols SOP/012/01.0
13. Review of Protocol Amendments SOP/013/01.0
14. Continuing Review of Study Protocols SOP/014/01.0
15. Review of Final Reports SOP/015/01.0
16. Non-Compliance/Violation Intervention SOP/016/01.0
17. Response to Participants’ Requests SOP/017/01.0
18. Management of Study Termination SOP/018/01.0
19. Review of Serious Adverse Events (SAE) Reports SOP/019/01.0
20. Site Monitoring Visit SOP/020/01.0
21. Agenda Preparation, Meeting Procedures and Minutes SOP/021/01.0
22. Emergency Meeting SOP/022/01.0
23. Communication Records SOP/023/01.0
24. Maintenance of Active Study Files SOP/024/01.0
25. Archive and Retrieval of Documents SOP/025/01.0
26. Maintaining Confidentiality of IEC/IRB’s Documents SOP/026/01.0
27. Audit and Inspection of the IEC/IRB SOP/027/01.0
SUBMISSIONS

- Protocol
- Informed Consent Form
- ADDITIONAL
Conflicts of Interest
Declaration & Management
(Financial/ Academic)
TYPES OF REVIEWS

- Exemption
- Expedited Review
- Full Review
- Continuing Review
- Modifications & Amendments
EXEMPTIONS

Proposals which **INVOLVE LESS THAN MINIMAL RISK** fall under this category.

- **Minimal risk:** Defined as one which may be anticipated as *harm or discomfort not greater than that encountered in routine daily life activities* of the general population or during the performance of routine physical or psychological examinations or tests.
Research proposals which do not involve living human participants or data derived from them may be exempt from IEC review. e.g.

- Audits of educational practices
- Research on microbes cultured in the laboratory
- Research on immortalized cell lines
- Research on cadavers or death certificates provided such research reveals no identifying personal data
- Analysis of data freely available in the public domain
RESEARCH CANNOT BE CONSIDERED LOW RISK
EXEMPTION PROCESS
The decision regarding request for exemption from review, signed by the IEC Member Secretary / Chairperson, is forwarded by the Secretariat to the Principal Investigator after the decision regarding the exemption is taken.

The Member Secretary informs the IEC of the decision at the next regular meeting and minutes it in the meeting notes.
EXPEDITED REVIEW

- A procedure through which certain research proposals may be reviewed and approved by a subcommittee without convening a meeting of the full Board.

- **PROPOSALS INVOLVING NOT MORE THAN MINIMAL RISK TO RESEARCH PARTICIPANTS** may be subjected to expedited review.
EXPEDITED REVIEW MAY BE CONDUCTED ONLY IF THE STUDY INVOLVES:

- Previously approved study submitted for continuing review with no additional risk
- Activity is limited to data analysis or health record research
- Anonymous surveys and retrospective chart reviews
- Analysis of discarded pathological specimens / stored paraffin blocks without personal identifiers
- Proposals involving previously banked materials and/or tissues as per policies of respective authorities like – tumour tissue repository
- Research activities that involve only procedures listed in one or more of the following categories:
  
  Clinical studies of drugs and medical devices only when -
  
   i. Research is on already approved drugs except when, Study of drug interaction or Conducting trial on vulnerable population
   
   ii. Adverse Event (AE) or (ADR) of minor nature is reported
Research involving clinical materials (data, documents, records, or specimens) that have been collected for non-research (clinical) purposes

Emergency Situations- serious outbreaks or disasters a full review is not possible, prior written permission of IEC may be taken before use of test intervention. Such study can be approved for pilot study to study safety and efficacy of intervention.

Research on Disaster Management- essential, culturally sensitive, extra care, provide benefits etc.
STUDY RELATED DOCUMENTS ELIGIBLE FOR EXPEDITED REVIEW
EXPEDITED REVIEW PROCESS
FULL REVIEW

All research studies *WITH MORE THAN MINIMAL RISK AND WHICH DO NOT QUALIFY FOR EXEMPTION OR EXPEDITED REVIEW, OR INVOLVE VULNERABLE POPULATIONS AND SPECIAL GROUPS*, should be subjected to full review.
Steps In IEC Review

IEC date fixed → Submissions made by researchers → Decide primary and secondary reviewers → Send proposals → Review

The IEC meeting → The discussions → The decision → Documenting the discussions and decisions

Communicate the decisions to researchers → Revisions/resubmissions/cleared

http://icmr.nic.in/bioethics/cc_bioethics/presentations/haryana/session11.pdf
Review research before initiation
FORMS, CHECKLISTS & FORMATS
IRB DECISION MATRIX

**BENEFICENCE**
- Risk/Benefit Analysis
- Experimental Design
- Qualifications of PI

**JUSTICE**
- Subject selection
- Inclusion/exclusion
- Recruitment

**RESPECT FOR SUBJECTS**
- Informed consent
- Surrogate consent
- Assent
- Privacy & Confidentiality
- Protection of subjects (especially vulnerable populations)
REVIEW PROCEDURES

- Review
- Evaluate
- Screen
- Deliberate
- Store
- Plan
- Check
- Monitor
- Protect
INFORMED CONSENT & CONSENT PROCESS
 AMENDMENTS & MODIFICATIONS

Amendments made to protocols or any other amendments related to the study may not be implemented until reviewed and approved by the IRB.
CONTINUING REVIEW

The purpose of continuing review is to **monitor the progress of the study which was previously been approved; not only for the changes but to ensure continued protection of the rights and welfare of research subjects.**
Protocol Deviation & Violations
DECISION MAKING PROCESS
DECISION MAKING

- Review research protocols to:
  - Approve
  - Modify/ revise
  - Disapprove/ reject
  - Suspend or terminate
COMMUNICATION TO PI

- Submission form with checklist for required documents and content of protocol
- Receipt of application with documents signed & dated
- Seek clarifications if any
- Based on SOP invite PI to present
- Ask for more information in writing if required
- Communicate regarding status in writing within a reasonable time
  - (a) Its trial-related decisions/opinions.
  - (b) The reasons for its decisions/opinions.
  - (c) Procedures for appeal of its decisions/opinions.
- Communicate if proposal requires waiver of review/consent
COMMUNICATION TO PI

- Amendments to protocol, ICD, protocol deviation/ violations
- Updated documentation eg. CV
- Report of the trial status annually or more frequently if requested
- Serious Adverse Events as per regulatory requirements
- Final report on completion/ termination of the project
COMMUNICATION TO DCGI

- Any change in composition of Ethics Committee.
- Change of PI
- SAE causality analysis & compensation within 30 days after receipt of analysis from PI within 14 days
COMMUNICATION TO PATIENT

- In the event of written complaint received from patient an expedited or full committee meeting to be held based on the IEC SOP.
- Decision taken will be communicated in writing and redressal action taken in consultation with institutional head.
- When a participant raises doubts about a protocol or its practice....
- Answer all the questions honestly and fully, in a language that she/ he can understand.
CERTIFICATE

- Approval with date of meeting & name of Ethics Committee
- Other information
- Members of Ethics Committee
- Signed by Chairman / Member Secretary
RECORD KEEPING
Monitoring of Research

- Once IEC gives a certificate of Approval
  - Work is done, do not think of it as duty to monitor
  - Oversight Mechanism in place
- Actual Site Visits
- Problem
  - Time, financial constraints
MONITORING PROCEUDRE

Who should be monitored?
How to monitor?
When to monitor?
Risk category

High
- Require more intensive and frequent monitoring of data and compliance with human participant protections.

Medium
- A random sample of medium-risk studies would provide random checks within the system and serve as an educational opportunity to instruct research staff.

Low
- Would not require onsite visits, just as they often are not subject to continuing review by the Research IRB.
MONITORING

- After approval, an oversight mechanism should be in place.

- **Actual site visits** can be made especially in the event of reporting of adverse events or violations of human rights.

- Additionally, **periodic status reports must be asked** for based on the safety concerns and this should be specified in the SOP of the IEC.

- **SAE reports** from the site as well as other sites are reviewed by EC and appropriate action taken when required.

- IEC may also seek **reports of monitoring** done by the sponsor and the recommendations of the DSMB may also be sought.
ETHICS REVIEW – TIME INTERVAL BASED

PERIODIC REVIEW
- The ongoing research reviewed at regular intervals of six months to one year as may be specified in the SOP of the ethics committee.

CONTINUING REVIEW
- Continue review of approved projects for continuation, new information, adverse event monitoring, follow-up and later after completion.

INTERIM REVIEW
- For special circumstances - instead of waiting for the scheduled time of the meeting
- Mechanism - sub-committee
  - re-examination of a proposal already examined by the IEC
  - any other matter which should be brought to the attention of the IEC.
ADMINISTRATION AND MANAGEMENT
ADDITIONAL SAFEGUARDS FOR SPECIAL & VULNERABLE GROUPS

disease/condition

age

poor

students

Institutionalised

children

mentally ill

uneducated

employee

military

pregnant

prisoners

tribals
An erosion of public trust...
Recent Amendments in D & C Rules

- Amendment vide G.S.R. 53(E) dated 30-01-2013 –
  - analysis of SAEs,
  - provisions for payment of compensation,
  - expansion of responsibilities of Investigator, Sponsor and EC,
  - amendment in ICD.

- Amendment vide G.S.R. 63(E) dated 01-02-2013
  - conditions for conduct of CT,
  - authority for CT inspections
  - actions in case of non-compliance

- Amendments vide G.S.R No. 72(E) Dated 08.02.13 –
  - requirements and guidelines for registration of Ethics Committee

- Amendment vide GSR 292 (E) 24.04.2014
ADDED RESPONSIBILITIES
In case of injury subject shall be provided free medical management as long as required.

In case of CT related injury or death subject is entitled for financial compensation as per order of DCG(I)- over and above expenses incurred on medical management.

The expense on medical management and financial compensation shall be borne by the Sponsor.

Sponsor shall give an undertaking alongwith the CT application to provide compensation in case of CT related injury or death.

In case of failure to provide medical management and/or compensation

- CT can be suspended / cancelled
- Sponsor can be restricted from conducting future CTs
Rule 122DAC

- Permission to conduct clinical trial
- LA may impose additional conditions in respect of specific clinical trials
- Sponsor-, employees, subsidiaries, branches, agents, contractors, sub-contractors, investigators, clinical trial sites if do not comply with conditions- LA issue warning letters, reject or discontinue study, debarr Investigator/sponsor/employees, subsidiaries etc to conduct any trial in future.
Rule 122 DAC: Permission to conduct Clinical trials

- EC approval
- Registry at CTRI
- Annual status report to CDSCO
- Sponsor (and their subsidiaries, branches, agents, sub contractors) liable for inspection by CDSCO
- CDSCO can reject/discontinue a trial or suspend/cancel the permission and can debar the investigator(s) and/or sponsor
Rule 122DD – Ethics Committee Registration

- No Ethics Committee shall review and accord its approval to a clinical trial protocol without prior registration with DCG (I).

- An application for registration of Ethics Committee is required to be made to DCG(I) as per Appendix VIII of Schedule Y.

- The Ethics Committee shall approve the CT and conduct periodic review as per the provisions of Schedule Y and the GCP Guidelines and other applicable regulations.
Rule 122 DD: Registration of Ethics Committee

*Pertains to approvals for clinical trial protocols*

EC liable for inspections by CDSCO

EC to grant approval and also to carry out review of ongoing trials

Mandate of EC expanded and EC to file reports regarding SAEs directly to CDSCO
**REQUIREMENTS**

- Compulsory registration with CDSCO of all ECs reviewing regulatory clinical trials to approve Clinical Trials or BA/BE studies in India

- Registration of ECs in accordance with requirements of Appendices VIII of Schedule Y

- ECs that **do not want to approve Clinical Trials or Bioavailability studies** need not register with CDSCO
**CHANGED RESPONSIBILITIES**

- Registered ECs have to **analyze SAE** and forward its opinion to DCGI (As per newly added appendix XII)

- ECs will allow **CDSCO to inspect/ verify** its records.

- Initial registration of all ECs is granted for **3 YEARS** by DCGI.

- Any change in the EC members should be notified to DCGI

- Maintain all documents for audit/inspection by DCGI
**CHANGED RESPONSIBILITIES**

- Qualification of Basic Medical Scientist and Clinician
  - Min PG after MBBS (preferably one pharmacologist)

- Special case - HIV, genetic patient groups may be represented in EC

- Experts can be invited as and when required; No decision making power to such guest experts

- COI policy- All EC members sign COI declaration form

- Person with COI-
  - Prior disclosure to chairperson
  - Should not take part in decision
  - Record COI in minutes of meeting.
RECORDS TO BE MAINTAINED BY IEC

- Composition of EC
- CV of all EC members
- SOPs
- National and International guidelines
- Copy of CRF, IB, protocol, data collection formats, etc.
- Agenda and minutes of all EC meetings (Sign of chairperson on each page of minutes)
Records to be maintained by EC

- Copy of all communication with EC members and PI (regarding application, decision and follow-up)

- All notifications for suspend/termination of a study with reasons

- Final report of the study (microfilms, CD or any video recording etc.)

- Time of record maintenance - Min 5 yrs from the date of termination of a study (both in hard and soft copy)
TRAINING OF EC MEMBERS

- EC members should be conversant with Human Protection, Schedule Y, Indian GCP and other regulatory requirements to safeguard rights, safety and well being of trial subjects
GSR No 53(E) Dt 30 Jan 2013

- Insertion of Rule 122 DAB: Compensation in case of injury or death during Clinical trial
  - Injury to the trial subject – *Free medical management as long as required*
  - Trial related injury – Medical cost + compensation
  - Trial related death: Compensation to nominee

- Cost of compensation to be borne by sponsor
HOW MUCH COMPENSATION?

GUIDELINES FOR DETERMINING QUANTUM OF FINANCIAL COMPENSATION TO BE PAID IN CASE OF CLINICAL TRIAL RELATED INJURY OR DEATH

GUIDELINES FOR DETERMINING QUANTUM OF FINANCIAL COMPENSATION TO BE PAID IN CASE OF CLINICAL TRIAL RELATED INJURY OR DEATH
GUIDELINES FOR DETERMINING QUANTUM OF FINANCIAL COMPENSATION TO BE PAID IN CASE OF CLINICAL TRIAL RELATED INJURY OR DEATH

Compensation = \( B \times F \times R / 99.37 \)

- **B**: Base Amount (8 lakhs)
- **F**: Factor depending on age (Workmen Compensation Act)
- **R**: Risk Factor (severity & seriousness, co-morbidities etc 0.5-4.0)

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GUIDELINES ON AUDIO-VISUAL RECORDING OF INFORMED CONSENT PROCESS IN CLINICAL TRIAL

DRAFT GUIDELINES ON AUDIO-VISUAL RECORDING OF INFORMED CONSENT PROCESS IN CLINICAL TRIAL

CENTRAL DRUGS STANDARD CONTROL ORGANIZATION
DIRECTORATE GENERAL OF HEALTH SERVICES
MINISTRY OF HEALTH & FAMILY WELFARE
GOVT. OF INDIA
9th JAN, 2014
ISSUES WITH AV RECORDING

- Privacy and consent for recording
- Technical aspects of storage and archiving
- Recording in large community based studies
- Illiterate and vulnerable subjects
POSSIBLE ALTERNATIVES

- Independent witnesses
- Consent for videotaping
- Videotaping for vulnerable population
“An audio-video recording of individual subject (including impartial witness, legally acceptable representative, whenever applicable) confirming that the informed consent document has been fully explained and has been well understood and that the subject is voluntarily participating in the clinical study, shall be maintained by the investigator for record”
CHANGING ENVIRONMENT
Present Status in India
ROLE OF ETHICS COMMITTEES ENHANCED

Registration of Ethics Committees has been made mandatory

F. No. DCG(I)/MISC/2012-
Directorate General of Health Services
Central Drugs Standard Control Organisation
Office of Drugs Controller General (India)
GREATER POWER TO ETHICS COMMITTEES

The Schedule Y of Drugs & Cosmetics Rules specifies that it is the responsibility of ethics committee that reviews and accords its approval to a trial protocol to safeguard the rights, safety and well being of all trial subjects. The ethics committee should exercise particular care to protect the rights, safety and well being of all vulnerable subjects participating in the study. The Committee should also make, at appropriate intervals, an ongoing review of the trials for which they review the protocol(s).

The Ethics Committee involved in clinical trials in the country is hereby requested to keep vigil on clinical trials being conducted under their jurisdiction. Further, if necessary you may make surprise visit to ensure that clinical trial is being conducted as per the requirements of Schedule Y of Drugs & Cosmetics Rules, GCP guidelines and other applicable regulations to ensure that the rights, safety and well being of the subjects involved in clinical trials in the country are protected.

If any deviation is observed at any point of time, you are requested to take remedial measures and also inform the Office of DCG (I) to take appropriate action in the matter.

F. No. DCG(I)/MISC/2012-
Directorate General of Health Services
Central Drugs Standard Control Organisation
Office of Drugs Controller General (India)
EMERGING ISSUES

- Compensation in Investigator initiated trials?
- Accreditation of trial sites, ECs and investigators
- Interpreting foreign trial data for regulatory decisions
- Compensation on compassionate grounds?
ETHICS COMMITTEE: CHALLENGES

- Independence
- Competence
- Training
- Conflict of interest
- Resources
Transfer of Biological Material (MOHFW Guidelines 1997)
INTERNATIONAL COLLABORATION/REGULATORY TRIALS

- IEC approval of Indian site mandatory
- If multicentric all local sites should approve the proposal
- Both foreign and India IEC hold meeting simultaneously to cut down on delay
- Regulatory/ HMSC approval must befo
8 Universal Ethical Requirements

1. Social Value
2. Scientific Validity
3. Fair Selection of Subjects & Communities
4. Favorable Risk-Benefit Ratio
5. Independent Review
6. Individual Informed Consent
7. Respect for Enrolled Subjects & Communities
8. Collaborative Partnership

“...must be adapted to the local health, economic, cultural and technological circumstances. For instance, disease risk effects risk-benefit evaluation.”

Ezakiel Emmanuel et al 2003
Clinical trials hold enormous potential for benefiting patients, improving therapeutic regimes and ensuring advancement in medical practice that is evidence based. Unfortunately, the data and reports of various trials are often difficult to find and in some cases do not even exist as many trials abandoned or are not published due to "negative" or equivocal results. However, this tendency for availability of only selective information from the myriad clinical trials conducted is not commensurate with the practice of "evidence-based medicine". Today, world over, a need has been felt on the imperative for transparency, accountability and accessibility in order to re-establish public trust in clinical trial data. And this would be feasible only if all clinical trials conducted are registered in a centralized clinical trials registry. Registration of trials will ensure transparency, accountability and accessibility of clinical trials.

Clinical Trials Registry-India (CTRI)

The Clinical Trials Registry-India (CTRI), hosted at the ICMR's National Institute of Medical Statistics (http://nims.icmr.nic.in), is a free and online public record system for registration of clinical trials being conducted in India that was launched on 20th July 2007 (www.ctri.nic.in). Initiated as a voluntary measure, since 15th June 2009, trial registration in the CTRI has been made mandatory by the Drugs Controller General (India) (DCGI) (www.cdso.nic.in). Moreover, Editors of Biomedical Journals of 11 major journals of India declared that only registered trials would be considered for publication.1, 2.

Today, any researcher who plans to conduct a trial involving human participants, of any intervention such as drugs, surgical procedures, preventive measures, lifestyle modifications,
MISSION

To safeguard and enhance the public health by assuring the safety, efficacy and quality of drugs, cosmetics and medical devices.
NEED FOR LAWS RELATED TO BIOMEDICAL AND BEHAVIORAL RESEARCH

- Inadequate regulations to stop violations of ethical norms
- Availability of naive subjects and ignorant researchers
- Inadequate knowledge of ethical review procedures when India is emerging as a global hub
- Participation in research for access to drugs, payment/compensation
- Provision for Offences and penalties
THE BILL

THE BIOMEDICAL AND HEALTH RESEARCH REGULATION BILL
2015
**SCOPE**

- Regulate biomedical and health research on human participants to ensure safety & well being
- Setting up of Biomedical Research Authority
  - Ensure that research is in accordance with basic ethical principles
  - Grant registration to institutions
  - Evaluate & monitor functioning of IECs
  - To effect changes in ethical guidelines from time to time
  - To provide relief in cases of violation and exploitation
FERCAP – SIDCER Recognition Process

1. Human Subject Protection Course — 3 days
2. Developing SOPs- 3 days
3. Self Assessment Checklist & Evaluation by Fora
4. Survey and Evaluation- 4 day site visit
5. Recognition- FERCAP Annual Conference
INTERNATIONAL SIDCER RECOGNITION
AWARDED TO
TMH & KEM HOSPITAL, MUMBAI IN CHIANG MAI, THAILAND 2009,
SGPGI LUCKNOW IN DAEGU, KOREA IN 2011,
PSG COIMBATORE IN COLOMBO, SRI LANKA IN 2012, NIRT CHENNAI IN 2013
NIE, CHENNAI, YRG CARE, CHENNAI AND NIRRH MUMBAI 2014
NEED TO DEVELOP A QUALITY CULTURE IN ETHICAL REVIEW PROCESSES

THANKS!!