Accreditation of Institutional Ethics Committees

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Investigator Capability vs Regulatory scenario: India

1988: Clinical trials made mandatory for all new drug introductions – Schedule Y
1995: Phase I & II studies for locally discovered New Chemical Entities
2000: Implementation of Indian guidelines on GCP
2002: Amendments to schedule Y to allow parallel phase clinical trials

Acknowledgement: Dr. Bakhle (OPPI)
Clinical Trial Gaps – Level of Risk

- Participant protection
- GCP Compliance
- Safety Reporting
- Site Infrastructure
- Data Quality

20-01-2015
Recommendations

• Prioritization of Clinical Trials
• Ethics Review Mechanisms
• Regulatory Capacity building
• Expertise building
• CRO registration
• Clinical Trial Registry
Recommendations – Ethics Review Mechanisms

1. Vigorous training of ethics committee (EC) members needed

2. System for accreditation of ECs and continuous review of their performance to be set up

3. SOPs for ECs must include types of information and infrastructural facilities and functioning processes

4. SOPs should distinguish between scientific and ethical review of trials and simultaneously enable a system for combined review as well.

5. For preventive trials (vaccine) community involvement should be mandated

6. While elements of informed consent forms are well laid out, the SOP for implementing these forms need to be standardized.

7. Harmonization of guidelines and rules between different parts of the regulatory process and Departments outside MoHFW

20-01-2015
Disparities in Infrastructure
Recent Ethical Issues - India

Bhopal

HPV Vaccine

20-01-2015
Maharaja Yeshwantrao Hospital, Indore

For 7 years - 73 clinical trials including 3,300 patients (1,833 children)

Ethics Committee Chairperson states EC has lost control – BBC News
Most Difficult EC Membership Challenges

• Defining Lay members
  – include patient representatives, ethicists, social workers, psychologists, priests and lawyers.

  – NHS, UK: ‘non-medical clinical staff who have not practised their profession for a period of at least five years’

• Absent legal experts
Revised ICMR Guidelines - Ethics Committees

Based on WHO Guidelines

Expanded: mostly based on US Guidelines but modified
Operational Guidelines & Surveying and Evaluating Ethical Review Practices, WHO

Standards and Operational Guidance for Ethics Review of Health-Related Research with Human Participants
Supreme Court Judgment 3.1. 2013

• Systems for proper conduct & monitoring of clinical trials
• Constitution of committees by MoH
  – To develop systems
  – Expert Committee for Aes/ ADRs
  – Technical Committee
  – Apex Committee
Accreditation - Need

• Improve knowledge and practice of research ethics among various health research stakeholders

• To strengthen human research protection programs

• To promote standard for quality

• To encourage institutional commitment to scientifically and ethically sound research with continuous improvement
Benefits of Accreditation

• Benefits to Government
  – Assists Government in discharging its duty for protection of public
  – Improves acceptance of regulations

• Potential benefits to public
  – Ensures that adequate safeguards are in place to protect well-being of the research participants drawn from the public

Public trust in research increases
Quality Ethics Review and Capacity Building of EC

• Establishment of competent ECs

• Providing regular training and continuing education in research ethics

• Place a sustainable communication network

• Effective & trustworthy collaboration between various stakeholders
Accreditation Agencies

- SIDCER
- AAHRPP

Voluntary Recognition/ Accreditation
Public sectors
TDR, OHRP, ICMR, Fogarty

Private Sectors
- IFPMA
- Phrma
- WIRB

NGOs - EFGCP
- ACRP
- PATH

SIDCER

FERCAP  FLACIES  FECCIS  PABIN  FOCUS

National   National   National   National   National
Chapters   Chapters   Chapters   Chapters   Chapters

Strategic Initiative for Developing Capacity in Ethical Review
Distribution in FERCAP Region

- Australia
- Bangladesh
- Bhutan
- Sri Lanka
- Malaysia
- Myanmar
- Korea
- Nepal
- Philippines
- Samoa
- Taiwan
- Singapore
- Lao
- Japan
- Vietnam
- Cambodia
- Indonesia
- FERCAP
- FERCIT
- Thailand
- FERCIN

Date: 20-01-2015
FERCI
(Forum for Ethical Review Committee in India)

- National Chapter of FERCAP in India
- Steering Committee constituted in Dec. 2002
- Registered 2006
- Accounts set up 2007
- Series of workshops in 2008 with other organisations like Industry related bodies like Indian Society of Clinical Research, FICCI & CII
Self Assessment (ICH GCP)

- Corrects structural and membership issues
- SOP revision
- Address procedural issues (review and post review)
- Forms and checklist revision
- Ordering files and archives
Standard Operating Procedure Course

Main Parts of SOP
• Structure and Membership
• Review Procedures
• Meeting and Decision Making Procedures
• Post Review Procedures
• Communication, Documentation and Archiving
• Preparing SOPs
Standard Operating Procedures (SOPs) - All IEC activities

- Constituting IEC
- Selection/Tenure
- Confidentiality agreements
- Training of members
- Consultants
- Submission procedures
- Pre-meeting Assessment
- Initial review
- Expedited Review
- Amendment of protocols
- Continuing Review
- Final Report
- Non Compliance
- Response to subject’s request
- Study Termination
- Management of SAEs
- Site Monitoring
- Agenda and Minutes
- Emergency Meetings
- Communications
- Filing & confidentiality
- Audit & Inspections

2011 WHO Guidelines – 10 standards
Site Visit

• Criteria

  – Appropriate structure and composition
  – Adherence to operating procedures
  – Completeness of review procedures
  – Appropriate post review procedures
  – Good communication, documentation and archiving procedures

20-01-2015
Objectives of an EC Survey

✓ To facilitate and support procedures for assisting the development of QUALITY and TRANSPARENCY in ethical review

✓ To review and provide feedback on practices and performance of ethics committees vis-à-vis established standards of ethical review

✓ To allow for an independent evaluation of the EC
Survey Requirements

• Accomplishment of Self Assessment Tool to judge EC readiness for survey

• EC members trained in human subject protection

• Comprehensive SOPs in place

• Integration of international and national guidelines into ethical review practices
Survey Methodology

1. Review of EC Self Assessment Form

2. Document review:
   SOPs, protocols, agenda and minutes of meetings, SAE reports, membership and staff files

3. Observe an EC full-board meeting

4. Office visit

5. Interview

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Conducting SIDCER Survey

- Conduct the opening meeting
- Presentation, discussions and review of the legal and regulatory frame work
- Tour of EC facilities
- Review of EC membership and staff
- Review of EC SOP
- Interview of EC representatives
- Review protocol files, meeting agenda/minutes and communications
- Review SAE, annual, final and site visit reports
- Observe board meeting
- Hold summary meeting
- Conduct closing meeting

20-01-2015
AAHRPP Accreditation
AAHRPP Accreditation

- Association for the Accreditation of Human Research Protection Program, Inc. [http://www.aahrpp.org/](http://www.aahrpp.org/)

- Steps in Accreditation Process:
  - Application preparation
  - On-site evaluation
  - Council review
  - Notification of accreditation status
AAHARPP Accreditable Organizations

1. Academic institutions
2. Clinical research organizations
3. Contract research organizations
4. Government agencies
5. Hospitals
6. Independent Review Boards
7. Private corporations
8. Research sites
AAHARPP Accreditation Process

• Before applying obtain organizational commitment for self assessment

Step 1

1. Submit application
2. AAHRPP reviews and provides feedback
3. Organization responds, awaits AAHRPP approval

Step 2 After getting approval

1. AAHRPP conducts site visit and issues report
2. Organization responds
3. AAHRPP’s Council issues final site visit report with accreditation determination

• Renewal of accreditation every 3 years

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Accredited IEC in India

• SIDCER
  – Tata Memorial Hospital, Mumbai (Renewal)
  – Seth G. S. medical College, Mumbai (Renewal)
  – SGPGI, Lucknow (For renewal)
  – PSG Medical College, Coimbatore
  – NIRT (ICMR), Chennai
  – NIRRH, Mumbai
  – NIE, Chennai
  – YRG Care, Chennai

• AAHRPP
  – Manipal hospital, Bengaluru (Renewal)
  – Kasturba Medical College, Manipal (Renewal)
  – Jehangir Clinical Trial Unit, Pune (Renewal)
  – Sahyadiri Hospital, Pune
  – Tata Memorial Hospital, Mumbai
Indian Accreditation of EC – 3 years

- Composition
- Adequacy of Administrative support & management for IEC activities
- SOPs -16
- Review Process

20-01-2015
Monitoring

- Netherlands – yellow card warning or suspension
- UK – dummy review exercise with no. of ECs for comparing performances
- India – Suspension
Inspection by Regulators

• Not for cause, for cause

• Suspension

• Receipt of appeal

• Closure
Thank You