Regulating Ethics Committees
-The Indian Experience

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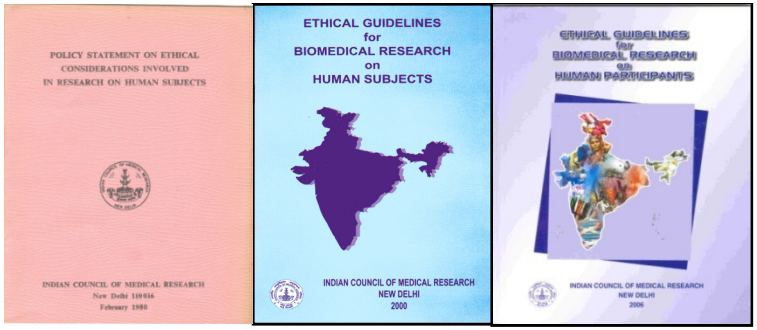
Institutional Ethics Committees
as Stakeholders

Directly Regulated research- Clinical Trials
Indirectly regulated -biomedical research

Main Tasks of Ethics Committee

- To safeguard welfare & rights of participants
- To ensure sound ethical/scientific decision making
- Look at competence, site facilities, appropriateness of research questions
- To promote ethically viable priority research
- Regular Monitoring
- Elements: Structure, function, competence, independence

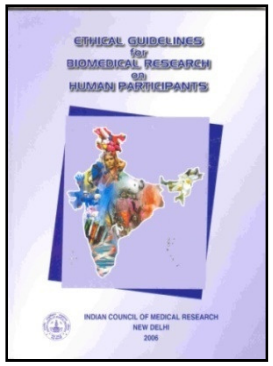
IEC in India



- First ICMR ethical guidelines were prepared by CECHR, under Justice H.R Khanna in Feb1980
  - 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
  - The oldest IECs were set up 3-4 decades ago (AIIMS,CDRI,SGPGI)

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), also referred to as Institutional Review Board (IRB) in many countries, 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 of the ethics till the same are completed.



Revised Guidelines, 2006

- There are also independent ethics committees [IEC(Ind)] functioning outside institutions for researchers with no institutional attachments/ institutions with no IEC
- Small institutions could form alliance with other IECs or approach IEC(ind)
- Large institutions/Universities can have more than one suitably constituted IECs
  - A sub-committee of the main IEC may review proposals submitted by UG/PG students
  - or if necessary, a committee may be separately constituted for the purpose

Indirect regulatory powers to ICMR Ethical Guidelines

(Direct regulations only for clinical trials)

- Revised Medical Council Act, 2002
  - For research practitioners should follow ICMR guidelines
- Revised Schedule Y of Drugs and Cosmetics Act, 2002, 2005
  - ICMR Ethical Guidelines should be followed for all clinical trials
  - For clinical trials the DCGI provides approval only on the condition that they will be reviewed and certified by an EC.
  - The EC has power to conduct an ethics review, initial and continuing review
  - EC has power to reject trials which do not conform to ethical standards laid down in the ICMR's ethical guidelines
  - ECs play the role of ethics regulator for the DCGI
  - EC can withdraw ethical approval of a research project if found necessary

Present Status in India

- Number of IEC's
- Institutional/ Independent/ Regional/ joint/ CRO
- Level of functioning
- Written SOPs
- Frequency of Meeting
- Authority/ terms of reference
- Composition/Quorum
- Quality of ethics review??
- If subjects are being adequately protected?
- If ethics committees follow regulations/ guidelines?
- IEC shopping??
- Awareness and training?

Roles & Responsibilities

Theoretically Understood

- Protect subject rights, safety & well being
- Competent, efficient, timely review
- Maintain ethical values
- Established in accordance with laws /regulations
- Documentation
- Privacy, confidentiality, justice issues
- Informed Consent
- Independent from political, institutional, professional, market influences

Need

Inculcate a Quality Culture in Ethics review?

Self Regulation vs External Regulation?

Can regulations help?

Self Regulation

- Presently IECs at different levels of functioning/ evolving
- Provides flexibility/ independence to IEC
- Chance to explore mechanisms
  - Review frequency/ by circulation/ review procedures
- Some have devised own internal regulatory systems as stated in SOPs
- Ethical Guidelines+ SOPs in detail can be very good and efficient self regulation and ensure quality

External Regulations

- Before having further regulations/ authority
  - need for more research on the present functioning/ performance
- period of experimentation with quality standards
- no independent assessment of the ethics review and its quality
- Significant lack of data on the effectiveness of IECs
- Lack of experience related to implementation issues
- Members often lack the requisite training/ education/skills for effective participation

Additional Regulations for IECs

- Further Regulations may hamper independence and functioning of IECs
- Fear that ethics committees become just another part of the administrative framework
- View that ethics committees may further delay research
- Whether research participants will be any better protected remains to be seen

Shortcomings of current system

- DCGI depends on ECs for implementing ethical standards in clinical trials
- There is no direct linkage of any kind between the DCGI and ECs.
- EC are not directly regulated by DCGI
- DCGI does not monitor the proper functioning of ECs
- ECs do not report to any authority that is responsible for supervising these committees and ensuring their proper and competent functioning.
- EC is the responsibility of institutions alone
  - ECs members are appointed
  - EC are financed by institutions and under their direct control

Other Issues

- CTRI only requires a mention of name of IEC & approval with no other details
- Need for local on site review by EC vs regional EC
- Review of multicentric research; single vs multiple
- Ethics Committees formed by Institutions & function as per Institutional requirements and may have direct COI
- Absence of transparency in the functioning of IEC and documents are kept confidential

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 for clinical trials
- Participation in research for access to drugs, payment/ compensation

The Bill

THE BIOMEDICAL RESEARCH ON HUMAN PARTICIPANTS REGULATION BILL

2011

Scope

- Promote & regulate biomedical and behavioral research on human subjects to ensure safety & well being
- Control and monitor the application of new technologies *eg.* stem cell research, therapeutic cloning, ART, Genomics etc.
- Restrict unscrupulous clinical trials on unsuspecting patients
- Provide legislative power to the ICMR Ethical Guidelines
- Setting up of a National Biomedical Research Authority

The Bill envisages oversight mechanism

- Creation of a National Biomedical Research Authority
- Setting up of a National Ethics Committee on Human Research
- Setting up a mechanism for registration of all Institutions and the committees involved in review of biomedical research

Functions of National Biomedical Research Authority

- Promote & ensure that research is in accordance with the basic ethical principles
- Grant recognition to institutions conducting biomedical research
- Evaluate & monitor functioning of IECs throughout the country
- To effect changes in ethical guidelines from time to time
- To provide relief in cases of violation and exploitation

Conclusion

- Most countries have regulations for clinical trials alone and very few have for all kinds of biomedical research
- If we have regulation ours may be among few countries in the world however this will be a way to handle ethical violations in research
- Having law alone will not solve problems and will be only the first step towards protecting participants as implementation of the law is the more crucial step.
- Regulations are needed to put a structure in place to punish those who violate principles, however do not ensure quality of ethical review or research

Conclusion

- Regulations may not directly lead to quality improvement in EC functioning
- Regulations can review composition and structure, however cannot probably cover all aspects related to functioning of IEC
- Ethical guidelines appended with detailed SOPs may be a good written framework
- EC review can be improved not by regulations alone but by having more and more training & education in research ethics

Thank you

- Education of Ethics Committee members
- Networking of member countries & other Fora
- Improve quality of ethical review practices