

# **A Beginner's Guide to setting up an Institutional Ethics Committee (IEC)**

**Workshop at the 2nd National Bioethics Conference,  
Bangalore, December 6 – 8, 2007**

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# FUNCTIONING OF IRBS/IECS

- Universal similarity – the focus of IRBs remain the safety and dignity of human participants in research studies
- Differences - regional variations and cultural nuances

***The effective functioning of such ethical review committees in both developed and developing countries depends on the internal learning, degree of autonomy and their ability to engage in best practices in a given context.***



# INTERNATIONAL GUIDELINES ON IRB/IEC

- Code of Federal Regulations, Title 45, Part 46, Subpart A, Section 46.102 (1991)  
([www.hhs.gov/ohrp/humansubjects/guidance/45cfr46.htm](http://www.hhs.gov/ohrp/humansubjects/guidance/45cfr46.htm))
- U.S. Food and Drug Administration (US FDA), 21 CFR Part 56  
([www.fda.gov/cber/ind/ind.htm](http://www.fda.gov/cber/ind/ind.htm))
- ICH – GCP, E6 (R1) (1996), Section 3 (1996)  
([www.ich.org/LOB/media/MEDIA482.pdf](http://www.ich.org/LOB/media/MEDIA482.pdf))
- World Medical Association Declaration of Helsinki (1964, last amended in October 2000), Section B.13  
(<http://www.wma.net/e/policy/b3.htm>)
- CIOMS International Ethical Guidelines for Biomedical Research involving Human Subjects (2002), Guidelines 2 and 3  
([www.cioms.ch/frame\\_guidelines\\_nov\\_2002.htm](http://www.cioms.ch/frame_guidelines_nov_2002.htm))
- Universal Declaration on Bioethics and Human Rights of UNESCO (October 2005), Article 19  
(<http://unesdoc.unesco.org/images/0014/001461/146180E.pdf>)



# INTERNATIONAL GUIDELINES ON IRB/IEC: SITUATIONS TO BE USED

- *Code of Federal Regulations, Title 45, Part 46, Subpart A*: Legal standard mandated by the US Federal Government for protection of humans in research
- *U.S. Food and Drug Administration (US FDA), 21 CFR Part 56*: Regulations established for clinical research by the US Food and Drug Administration
- *ICH – GCP, E6 (R1) (1996)*: Unified standard for European Union, Japan, and the US for clinical data
- *World Medical Association Declaration of Helsinki*: Official policy document of the World Medical Association, global representative body for physicians
- *CIOMS International Ethical Guidelines for Biomedical Research involving Human Subjects (2002)*: International ethical guidelines for biomedical research in developing countries
- *Universal Declaration on Bioethics and Human Rights of UNESCO (October 2005)*: Adopted by the General Conference of UNESCO



# ICMR GUIDELINES ON IRB/IEC

“It is **mandatory** that all proposals on biomedical research involving human participants should be cleared by an appropriately constituted Institutional Ethics Committee (IEC), also referred to as Institutional Review Board (IRB), Ethics Review Board (ERB) and Research Ethics Board (REB) in other countries, to safeguard the welfare and the rights of the participants....” (ICMR, 2006).  
([www.icmr.nic.in](http://www.icmr.nic.in))



# ICMR GUIDELINES (2006) - AN OVERVIEW

## Chapter II. Ethical Review Procedures (pages 8 – 20)

- Basic responsibilities
- Composition
- Terms of reference
- Training
- Regulation
- Review procedures
- Submission of application
- Decision making process
- Review process
- Periodic review
- Continuing review
- Interim review
- Monitoring
- Record keeping
- Administration and management
- Special considerations



# Chapter II. Ethical Review Procedures

## BASIC RESPONSIBILITIES

- Competent review
- Objective manner

### *Special situations:*

- *Small institutions - form alliance with other IECs or approach registered IEC*
- *Large institutions - more than one suitably constituted IECs for different research areas*



# Chapter II. Ethical Review Procedures

## COMPOSITION

- Multidisciplinary and multisectorial
- Independence and Competence – two hallmarks
- Number of persons: 8 - 12
- Quorum – minimum of 5
- Chairperson – outside the Institution
- Member Secretary – same institution
- Others – mix of medical/non-medical, scientific and non-scientific persons, lay persons from the community
- Adequate representation of age and gender
- Subject experts, if needed



# Chapter II. Ethical Review Procedures

## TERMS OF REFERENCE

- To include Terms of Appointment
- Specify these in the SOP
- SOP to be made available to each member
- Written SOPs – to be updated periodically based on the changing requirements
- Extension of membership for another term
- Preferable to appoint persons trained in bioethics or persons conversant with ethical guidelines and laws of the country
- Nomination of substitute member in case of continuous missing of meetings by a member due to illness or other unforeseen circumstances



# Chapter II. Ethical Review Procedures

## TRAINING

Be up-to-date with all national and international developments in ethics through:

- Orientation courses on related topics
- Regular training
- Good Clinical Practice for drug trial review
- Informed about any change in the regulatory requirements
- Aware of local, socio-cultural norms and economic context



# Chapter II. Ethical Review Procedures

## REGULATION

Registration of all IECs under a Biomedical Research Authority, to be set up under the proposed Bill on Biomedical Research on Human Participants (Promotion and Regulation)



# Chapter II. Ethical Review Procedures

## REVIEW PROCEDURES

- Before research is initiated, the IEC should review every research proposal on human participants
- Ensure scientific evaluation has been completed
- Evaluate the possible risks, expected benefits, privacy, confidentiality and the justice issues
- Screening of proposals by Member-Secretary/Secretariat
- Proposals to be categorized into three types – Exemption from review, Expedited review, and Full review



# Chapter II. Ethical Review Procedures

## SUBMISSION OF APPLICATION

- Application in a prescribed format along with the study protocol as prescribed in SOP of IEC concerned
- To include, among other details, study title, objectives, rationale for study etc.
- Plan to withdraw or withhold standard therapies in the course of the research
- Probable ethical issues
- Funding details
- Agreement to comply with national and international GCP protocols for clinical trials.



# Chapter II. Ethical Review Procedures

## DECISION MAKING PROCESS

- Complete and adequate review
- Periodic meetings at frequent intervals
- Review of new proposals
- Annual progress of ongoing studies
- Review SAE reports
- Assess final reports
- Meetings to be minuted, approved and signed by Chairperson/alternate Chairperson/designated member of the IEC

*Decisions to be based on broad consensus.*



# Chapter II. Ethical Review Procedures

## REVIEW PROCESS

- SOP to state review process
- SOP to clarify whether review to be done by all reviewers/primary reviewers
- Review to be done in formal meetings
- No decision through circulation of proposals
- Meetings at regular intervals



# Chapter II. Ethical Review Procedures

## PERIODIC REVIEW

- Six months to one year

## CONTINUING REVIEW

- For continuation, new information, adverse event monitoring, follow-up, after completion of project

## INTERIM REVIEW

- By a sub-committee



# Chapter II. Ethical Review Procedures

## MONITORING

- Need for oversight mechanism
- Actual site visits
- Periodic status reports
- SAE reports
- Reports of monitoring by sponsor and recommendations by DSMB, if needed by IEC



# Chapter II. Ethical Review Procedures

## RECORD KEEPING

- Documentation to be dated, filed and preserved per written procedures
- Strict confidentiality during access and retrieval
- Records for: composition of IEC, CV of IEC members, records of training, SOP, guidelines, protocols, correspondence, agenda, meeting minutes
- Records to be maintained for 3 years after completion/termination of study



# Chapter II. Ethical Review Procedures

## ADMINISTRATION AND MANAGEMENT

- Full time secretariat
- Record keeping space
- Members to be compensated reasonably
- Reasonable fees for review and administrative processes
- Allocation of reasonable amount of funds



# Chapter II. Ethical Review Procedures

## SPECIAL CONSIDERATIONS

Research involving:

- Children
- Pregnant and lactating women
- Vulnerable participants, and
- Those with diminished autonomy
- Issues pertaining to commercialisation of research
- International collaboration

*Observations and suggestions of IEC should be given in writing in unambiguous terms in such instances.*



# ANALYSIS OF ICMR GUIDELINES

## Strengths and limitations of ICMR Guidelines

- Strengths:
  - Clear cut guidelines
  - No ambiguity
  
- Limitations:
  - Allocation of amount for funding of IEC (in terms of percentage of total project grant) not given
  - No minimum qualifications for IEC members



# YRG CARE IRB

## *Best Practices*



# Best Practices at YRG CARE IRB

- ✓ Face to face interactions with investigators during IRB meetings.
- ✓ High standard of IRB review, including students' short term research proposals.
- ✓ IRB members kept informed about YRG CARE publications, and conference presentations.
- ✓ Translation and back translation of Informed Consent Forms mandatory.
- ✓ Joint IRB-CAB Meetings held annually.



# Best Practices at YRG CARE IRB

- Stability of IRB members
- No conflicting roles and hence independent of the institution
- Clear documentation procedures
- Access to files limited only to IRB Desk, and records kept under lock and key
- Archiving of completed project files in a Record Maintenance Unit (RMU), duly indexed
- Clarification of IRB procedures from different resources – both national (ICMR) and international (foreign collaborators)



# Best Practices at YRG CARE IRB

- Test of understanding for research participants of clinical trials
- Specimen banking form was introduced in informed consent forms very early
- Review of scientific content of proposals by a separate in-house committee, **prior** to IRB submission
- Screening of proposals from ethical viewpoint by the IRB Coordinator, a trained bioethicist, prior to IRB submission



# CONCLUSION

*Success of an IRB depends on:*

- The quality and engagement of members
- Procedures
- Documentation, and
- Institutional commitment - financial resources, degree of autonomy and investigator adherence to norms.



# Thank You

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