

**Fundamentals of Research Ethics and
 the Role of the Institutional Ethics Committees:
 Best Practices for the Review of Research
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**IEC BEST PRACTICES:
 INTERNATIONAL STANDARDS FOR
 MEMBERSHIP AND QUORUM REQUIREMENTS**

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STRUCTURE OF PRESENTATION


- I. IEC Membership and Quorum Requirements
- II. International Guidelines
- III. ICMR Guidelines
- IV. Schedule Y of Drugs and Cosmetics Act
- V. Differences in International and National Guidelines
- VI. Challenges
- VII. Best Practices
- VIII. Conclusion



**I. IEC MEMBERSHIP AND QUORUM
 REQUIREMENTS**

 **Importance of Membership and Quorum:**

- ◆ What should be the right composition of IEC members?
- ◆ Why is a quorum needed?



II. International Guidelines



- ✓ Code of Federal Regulations, Title 45, Part 46, [Subpart A, Section 46.107 IRB Membership, Section 46.108 IRB Functions and Operations](#) (1991) (www.hhs.gov/ohrp/humansubjects/guidance/45cfr46.htm) – 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, [Subpart B – Organization and Personnel, 56.107 IRB Membership, Subpart C – IRB Functions and Operations, 56.108 IRB functions and operations](#) (www.fda.gov/cber/ind/ind.htm) – Regulations established for clinical research by the US Food and Drug Administration



II. International Guidelines



IRB Membership (45 CFR 46 and 21 CFR 56):

- At least five members
- Varying backgrounds
- Diversity – race, gender, cultural backgrounds, sensitivity
- Promote respect – safeguarding rights and welfare of human subjects
- Knowledgeable persons – institutional commitments and regulations, applicable law, standards of professional conduct and practice, vulnerable category of subjects



II. International Guidelines



IRB Membership (45 CFR 46 and 21 CFR 56):

- Gender balance
- No one profession
- Primary concern in scientific area – one member
- Primary concern in nonscientific area – one member
- Non-affiliation with institution – one member
- No Conflict of Interest
- Invite individuals with competence in special areas – non-voting



II. International Guidelines



IRB Quorum (45 CFR 46 and 21 CFR 56):

- Review proposed research at convened meetings
- Majority of IRB members to be present
- To include at least one nonscientific member
- Approval of a majority of IRB members present



II. International Guidelines



✓ ICH – GCP, E6 (R1) (1996), [Section 3.2 Composition, Functions and Operations](http://www.ich.org/LOB/media/MEDIA482.pdf) (www.ich.org/LOB/media/MEDIA482.pdf) – Unified standard for European Union, Japan, and the US for clinical data

IRB Membership and Quorum (ICH GCP, E6 (R1)):

- Five members - at least
- Primary concern in nonscientific area – one member
- Independent of the institution / trial site – one member
- Decisions to be taken at announced meetings at which **quorum** as stipulated in SOPs, is present



II. International Guidelines



✓ CIOMS International Ethical Guidelines for Biomedical Research involving Human Subjects (2002), [Guideline 2 Ethical Review Committees, Subsection on Committee Membership](http://www.cioms.ch/frame_guidelines_non_2002.htm) (www.cioms.ch/frame_guidelines_non_2002.htm) - International ethical guidelines for biomedical research in developing countries



II. International Guidelines



IRB Membership and Quorum (CIOMS):

- Number of members and quorum – not specified
- Physicians, scientists, other professionals - nurses, lawyers, ethicists and clergy, lay persons
- Both men and women should be included
- Externally sponsored research to be reviewed by persons thoroughly familiar with customs and traditions of population or community concerned
- Representation from HIV/AIDS or paraplegia, uneducated or illiterate persons
- Declaration of Conflict of Interest



II. International Guidelines



Universal Declaration on Bioethics and Human Rights of UNESCO (October 2005), [Article 19](http://unesdoc.unesco.org/images/0014/001461/146180E.pdf) (<http://unesdoc.unesco.org/images/0014/001461/146180E.pdf>) –

Adopted by the General Conference of UNESCO

IRB Membership

"Independent, multidisciplinary and pluralist ethics committees should be established, promoted and supported at the appropriate level..."



III. ICMR Guidelines (Chapter 2)



Composition of IEC and Quorum Requirements

- Multidisciplinary and multisectorial
- Independence and Competence – two hallmarks
- Number of persons: 8 - 12
- Quorum – minimum of 5
- Adequate representation of age and gender
- Subject experts, if needed



III. ICMR Guidelines (Chapter 2)



Membership:

- Chairperson (who is not head of the Institution, to maintain the independence of the IEC),
- 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,
- Member Secretary



IV. Schedule Y, Drugs & Cosmetics Rules, 1945, Appendix VIII – Ethics Committee



Membership:

- Members – 7
- Chairperson (outside the institution)
- Member Secretary
- Mix of Medical/Non-medical, Scientific/Non-scientific including lay public
- Primary area of interest – non-scientific – one member
- Independent of the institution / trial site – one member
- Appropriate gender representation
- Subject experts – invitee
- Representation of specific patient groups, e.g. HIV AIDS, genetic disorders etc.



IV. Schedule Y, Drugs & Cosmetics Rules, 1945, Appendix VIII – Ethics Committee



Quorum:

- Members – 5
- Basic medical scientist (preferably one pharmacologist)
- Clinician
- One legal expert or retired judge
- Social scientist / NGO representative / philosopher / ethicist / theologian or a similar person
- Lay person from the community



**V. International and ICMR Guidelines:
A Comparison**



- Subcommittee for student proposals
- Approval by voting Vs. Approval by consensus



**VI. Challenges *before* constituting an
IEC:**



Inviting qualified members to join the EC:

- * Time and availability
- * Place of residence
- * Having a representative of the concerned community join the IEC
- * Familiarity with local customs for organizations not having CAB



**VI. Challenges *after* constituting an
IEC:**



- Δ Lack of experience with IRB processes and ethical guidelines
- Δ May not be aware of the issues to address, despite being highly qualified in their subject field



VII. Best Practices: Composition



- Stability of IRB members
- No conflict of interest
- Independent of the institution



VII. Best Practices: Training of EC members



- Δ International ethical and regulatory guidelines
- Δ On-line certification in Human Research Participants Protection
- Δ Good Clinical Practices training
- Δ Attend Bioethics workshops / conferences– national and international
- Δ Networking with IECs in other regions
- Δ Site visits
- Δ Continuing education



VIII. Conclusion



Success of an IRB depends on:

- The quality and engagement of members
- Level of commitment
- Degree of autonomy of members



Thank You!
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