

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:
DOCUMENTATION
AND
COMMUNICATION**

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STRUCTURE OF PRESENTATION

- I. IEC Documentation and Communication: Importance
- II. International Guidelines
- III. ICMR and Indian GCP Guidelines
- IV. Types of IEC Documentation
- V. Modes of IEC Communication
- VI. Challenges
- VII. Best Practices
- VIII. Conclusion



**I. IEC Documentation and
Communication: Importance**



FACILITATE EASY RETRIEVAL!



II. International Guidelines



- ✓ Code of Federal Regulations, Title 45, Part 46, [Subpart A, Section 46.109 \(d\) IRB Review of Research, Section 46.115 IRB Records \(1991\)](#)
(www.hhs.gov/ohrp/humansubjects/guidance/45cfr46.htm) –
- ✓ U.S. Food and Drug Administration (US FDA), 21 CFR Part 56, [Subpart C – IRB Functions and Operations, Section 56.109 \(d\) IRB Review of Research Section 56.115 IRB Records](#)
(www.fda.gov/cber/ind/ind.htm) –
- ✓ ICH – GCP, E6 (R1) (1996), [Section 3.4 Records ; Section 4.4. Communication with IRB/IEC](#)
(www.ich.org/LOB/media/MEDIA482.pdf)



II. International Guidelines



1. Copies of relevant documents
2. Meeting minutes
3. Records of continuing review activities
4. Copies of all correspondence between the IRB and the investigators
5. List of IRB members
6. Written SOPs for IRB
7. Statements of significant new findings provided to subjects
8. Written notification of IRB decision

RECORDS TO BE RETAINED FOR THREE YEARS



III. ICMR and Indian GCP Guidelines



RECORD KEEPING

- All IEC documentation and communication to be dated, filed and preserved according to written procedures
- Strict confidentiality during access and retrieval
- Records for: composition of IEC, CV of IEC members with records of training, SOP, guidelines, protocols, correspondence, agenda, meeting minutes **with Chairman's signature**, copies of Protocol, data collection formats, CRFs, Investigator's Brochures
- Copies of decisions
- Notification of study premature termination with reasons
- Final study report – **microfilms, CDs and Video recordings**

**RECORDS TO BE RETAINED FOR THREE YEARS (ICMR) /
FIVE YEARS (INDIAN GCP)**



IV. Types of IEC Documentation: Composition of the IEC/Roster



List of IRB members containing:

- Name of IRB member
- Earned degrees
- Representative capacity – e.g. scientific/nonscientific
- Indications of experiences – e.g. board certifications, licenses
- Institutional affiliation, if any, and occupation
- Gender
- Contact details: Address, Phone Number, Email ID
- To be signed and dated by IRB Administrator/ Member Secretary, and updated whenever there is a change in membership



IV. Types of IEC Documentation: Curriculum Vitae of the IEC Members



Maintain individual files for IEC members containing:

- CV (to be updated periodically), signed and dated
- Training programs attended
- Copy of invitation letter from IRB Chair / Institution to join IEC
- Original of consent letter signed by IEC members to join IEC
- Documentation on renewal of IEC membership, if applicable



IV. Types of IEC Documentation: Review Procedures & SOPs



- **Review Procedures for Regulatory Requirements**
 - Exemption from Review
 - Expedited Review
 - Full Review
 - Initial and Continuing Review
 - Reporting of unanticipated problems involving risk to participants
 - Non compliance
 - Suspension or termination of IRB approval
- **Operational Details**



IV. Types of IEC Documentation: Guidelines and Registration



- National and International ethical and regulatory guidelines followed by the institution's IRB
- Updated IRB Registration (OHRP) if institution has NIH-funded studies
- Updated Federal-Wide Assurance



IV. Types of IEC Documentation: IEC Application



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.
- Participant recruitment procedures and brochures, if any
- Informed Consent Forms in English and local languages
- Plan to withdraw or withhold standard therapies in the course of the research
- Proposed compensation and reimbursement of incidental expenses
- Probable ethical issues
- Funding details
- Agreement to comply with national and international GCP protocols for clinical trials



IV. Types of IEC Documentation: IEC Correspondence



Prior to the IEC Meeting

To investigators:

- Information on IEC meeting date to be informed to PIs in advance
- Deadline on IEC submission date to be notified
- Templates on IEC submission form, Continuing Review

To IEC Members:

- Meeting package to be delivered as per institutional policy
- Hard copies / CDs, as requested by IEC members



IV. Types of IEC Documentation: IEC Meeting Agenda



- New Protocols and ICFs
- Continuing Review
- Amendments
- Adverse Events
- Full Board approval of Expedited Review
- Correspondence
- Safety Reports



IV. Types of IEC Documentation: IEC Meeting Minutes



- Meeting date, venue, time / duration
- Meeting attendance – members, others, apologies
- Confirmation of previous meeting minutes
- IRB actions and votes – for, against, abstaining
- Entry / exit / recusal (due to COI)
- Quorum
- Approval / disapproval / modification / termination and their basis
- Waiver of consent
- Issues discussed with permission of IRB Chair
- Date and venue of next IRB meeting
- Time of meeting adjournment



IV. Types of IEC Documentation: IEC Decision Communication



In writing -

- Approve
- Modify
- Disapprove
 - o Statement of reasons for decision
 - o Opportunity to investigator to respond in person or in writing



**V. Modes of IEC Communication:
IEC Approval**



- Date of letter
- Addressed to PI
- Name of IEC
- Date, Time, Place of meeting
- Protocol Title (including Protocol Amendments), Version Number, Version Date
- Duration of Approval and date of validity/Annual Review due
- Informed Consent – English, Local Language Translation and Back Translation
- Investigator’s Brochure, Version Number, Version Date



**V. Modes of IEC Communication:
IEC Approval**



- Proposed methods for patient accrual
- Protocol deviation, if any
- Current CV of PI
- Insurance Policy / Compensation
- Investigator’s Agreement with Sponsor
- Investigator’s Undertaking
- Names of IEC members present at the meeting with designation
- To be signed and dated by the IRB Chair, with IRB seal duly affixed



VI. Challenges



- Storage space
- Retrieval of current IRB approvals
- Timeline
- Delay in getting approved papers in hand
- Bureaucratization
- Communication issues between IRB Desk and concerned department



VII. Best Practices



1. Approvals in place
2. Optimum use of available storage space – electronic
3. Timeline to be adhered to
4. Quick turnaround of papers
5. Indexing of documents to enable easy retrieval
6. Listing of projects by number
7. Replace files



VII. Best Practices



8. Files to be under lock and key – limited access
9. Print and file important documents and related email communication – immediately!
10. Tracking and controlling of version number and version date of important documents by IRB Desk
11. Maintain separate files for items
12. Regular quality check of IRB documentation




VIII. Conclusion



- ✓ Documents to be self explanatory
- ✓ Communication to be clear and specific

IF IT HAS NOT BEEN DOCUMENTED, IT HAS NOT HAPPENED!





THANK YOU!
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