Challenges For Independent Ethics Committees, experiences.

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Main Topics

Independent Ethics committee consultants . (IECC)

- Selection of members.
- Training of members especially in regulations.
- SOP
- Protocol Review
- Approval
- Site visits .
- Follow up
- Others.

IECC

About IEC Consultants:

- IEC Consultants is a registered partnership firm, registered in Bangalore, with **Reg. No. 2036/2004-2005**.
- The Income Tax **PAN No. is AABFI 8169D**.
- The Service Tax No. is **(TIC) AABFI 8169D DST 001**.
- **IEC Consultants operate in compliance with ICH-GCP, ICMR, Guidelines for Clinical Trials – CDCSO (India) and Schedule Y of Drugs & Cosmetics Act & Rules there under.**
- IEC Consultants have been allotted the FWA No. **FWA 00012967 by Federalwide Assurance, USA.**
- IEC Consultants are registered with the US FDA, and their Office for Human Research Protections (OHRP) have assigned the number IORG0006108 to our institutional review board (IRB) organization (IORG), representing the overall registration. Our distinct identification number is **"IRB00007355 I E C Consultants IRB #1".**

Selection of Members

- Follow the Rules & guidelines . Schedule Y, ICMR, Indian GCP and others.
- Qualification, gender and experience should be looked into.
- Normally there is no affiliation for Independent ethics committees.
- Registration Under? We don’t have a body in India for registration at the moment.
- Can be registered under FWA – IORG / Other International Organizations.

STANDARD OPERATING PROCEDURE

- Give all the details of what procedures you follow.
- Introduction.
- Purpose ,scope, responsibilities and composition of EC.
- Protocol review and approval procedures.
- Scientific Design.
- Research Participants, Informed consent , compensation .
- Decision making .
- Continuing review and follow up.
- Adverse events
- Archival.
- IEC members list and signature.

Review Process& Approval

- How do you make all the members read the Protocols?
- Our method: Protocol Review Summary (PRS) forms for BA/BE , Phase and other studies, have to be filled by every member. At the meeting these forms are read and discussed .
- Quorum—5 Members must be there with the specified people mentioned in the guidelines. Since certain people like lawyer , lay person and social worker may be a single member in a committee, you should have an alternate member for these and invite them when these are absent.
- Approval is by consensus . No voting.

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Review Process & Approval- Contd.

- Have a separate document called Terms and requirements to submit a protocol. This has a check list at the end for the documents to be submitted.

- A specialist in the subject may be invited for the meeting if necessary for phase studies.

  Questions are asked in the form of Record notes.

  Approval is by consensus according to rules. No voting.

Review & Approval Contd.

Usual Questions asked .BA/BE Studies:

- Date of manufacture and expiry for the test and reference drugs.
- If females are taken to inform the committee.
- Bunk beds cannot be used (where drug causes hypotension or hypoglycemia)
- DCGI permission if not received then submit it before the start of the study. Not necessary if it is an approved drug.
- If 2 foreign countries are involved then whether the drug will be available in India at a reasonable price.

Phase Studies. For phase studies we have a checklist for documents. –later

Conditional Approval may be given .Only DCGI permission and CTRI may be submitted before the study starts. Follow the Schedule Y format .

CHECK LIST

- **Request Letter for Review of Protocol**
- **Protocol Review Fee Cheque.**
- **Protocol Text**
- **CV of Principal & Co-Investigators**
- **Undertaking from CRO/Principal Investigator**
- **Informed Consent Document & Form**
- **ICD/ ICF Translations in regional languages**
- **Back translation/Translation Certificate of item 7**
- **Diet Chart, Patient Diary, Flow Chart, etc.**
- **Translations of Study Materials of item 9**

Check List

- **Back translation/Translation Certificate**
- **Text of material for recruitment of participants**
- **Copy of Application to/ Permission from DCGI**
- **Copy of Insurance Policy**
- **Compensation payment to Subjects**
- **Investigator's Brochure**
- **Case Report Form in English**
- **Number of Centers Worldwide / India**
- **List of Centres for Review by IEC Consultants**
- **Number of Subjects - Worldwide/India/IECC**

Check List

- **Description of Facilities at Study Centre**
- **NOL from Head of Institution of PI**
- **If other EC has gone through this Study and Rejected / Disapproved/ Conditionally Approved (Please attach copy of letter)**
- **NOL from Internal EC/IRB of any Centre**
- **CTRA, with financial agreement between Sponsor & Investigator.**
- **CTRI Registration Number**.

Site Visits

- Before a new site is approved.
- Have a check list for this also.
- When females are taken special facilities to be provided.
- For BA/ BE Studies . At least once a year if not twice for sites doing BA/BE studies. WE go for checking facilities and for dosing.

Follow up

Problems regarding follow up :

- The CRO s are not prompt in sending yearly report in spite of asking for it in the approval letter.
- Keep track of SAE s SUSARs , CIOMs Appendix XI etc .
- Deviations.
- Most important Death and compensation.

PIT FALLS in Ethics committees.

- Do not follow the guidelines in having a committee with proper no, designation or gender distribution.
- Quorum is not followed.
- Fastest Review and Approval without giving enough time. According Schedule Y there should be 3 weeks between submission and review and according to ICMR 2 weeks. Less time leads to approval without proper review.
- Some committees do not ask questions and no site visits are done.
- Specialists consultation must be done.

Auditors

- Auditing an ethics committee is good. They could give suggestions .
- But auditors should be thorough in rules and regulations .

Conclusion

- Ethics should not be forgotten when reviewing a protocol. Ethics and science should go hand in hand .
- Conflict of interest must be kept always in mind.
- Ask yourself whether you will undergo this clinical trial or you will allow your close relative to undergo this trial .


Thank you