

Improving Quality of Review

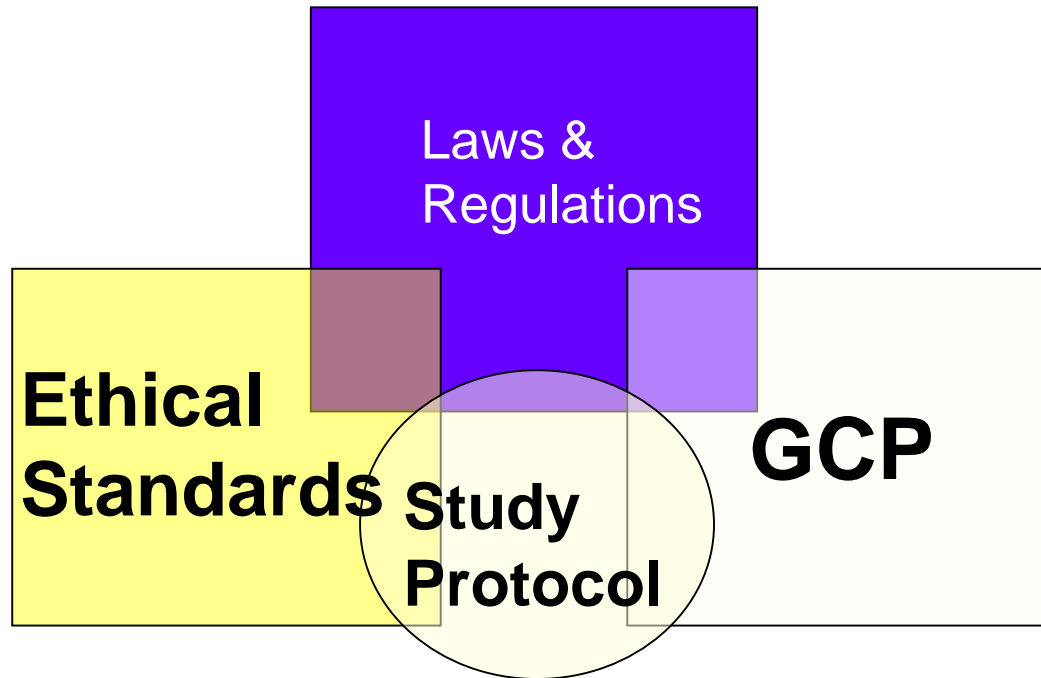
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**Forum for Ethical Review Committees
in the Asian & Western Pacific Region**

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Framework for Analysis of Protocols



Elements of Good Protocol Review

- Appropriate and competent primary reviewers
- Good assessment form
- Good meeting procedures
- Good documentation
- Appropriate secretariat support

Good Protocol Review

Appropriate and competent primary reviewers

- Protocol reviewer – Clinical expertise related to the protocol
- ICF reviewer – Non medical member

Good Protocol Review

Reviewers should

- Diligently reads the protocol details
- Conducts literature search
- Fills up the assessment forms with relevant comments

Good Protocol Review

Good Assessment Form

- Enables appropriate review of technical issues
 - Objectives
 - Design and methodology
 - Inclusion/ exclusion criteria
 - Scientific tools
 - Sample size
 - Analysis plan

Good Protocol Review

Good Assessment Form

- Enables appropriate review of ethical issues
 - Appropriate risk/ benefit ratio
 - Ethically sound design and methodology
 - Appropriate Inclusion/exclusion criteria
 - Addresses vulnerability issues
 - Addresses conflict of interest
 - Maintains confidentiality
 - Qualified research team
 - Appropriate site

Good ICF Review

Good ICF review checklist based on essential ICF elements

- Full disclosure of information
 - Same information found in the protocol
 - Compensation, medical care
 - Participant's responsibilities
- Comprehension
 - Use of simple terms and local language
- Voluntariness

Good Meeting Procedures



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Meeting Agenda

- Contains items to be discussed
 - Attendance (Quorum, COI Declaration)
 - Minutes of last meeting
 - New protocols
 - Resubmission
 - Amendments
 - Continuing review
 - SAE
 - Any others

Quality board meeting

Evidence of good preparation

- Before the meeting:
 - Agenda preparation
 - Ensuring quorum
 - Complete documents from PI (Protocol, ICF, instruments, CV, GCP training)
 - Appropriate reviewers who prepare their comments
 - Comprehensive assessment forms (scientific and ethical issues)

Quality board review

Good review practices during the meeting

Initial review

- Primary reviewer presentation
- Relevant comments about science
- Ethics review
 - Vulnerability assessment
 - Risks /benefits identified
 - Comments about protocol, information sheet/ consent form
- Appropriate board discussion of issues
- Appropriate decision
- Appropriate resubmission procedures

Quality board review

Continuing/ post approval review

- Amendments (protocol, ICF, research team)
- Progress report for renewal of approval
- SAE reports
- Protocol deviation
- Site visit
- Final reports

Quality board review

Continuing/ post approval review

- Appropriate channel for review (expedited/ full board)
- Reviewers familiar with initial review issues
- Maintain appropriate risk/ benefit ratio
- Linked to initial EC approval
- Patient safety is the primary concern

Good board meeting dynamics

- Chair presides and on top of discussion
- Members actively participate
- Medical/ scientific members provide technical and ethical comments
- Non medical comment about ICF and patient rights and safety
- Members freely give opinions
- Consensus/ decisions arrived at

Decision Making

- Approval
- Minor revision
 - Expedited review of required modifications
- Major revision
 - Full board review of required modification
- Disapproved
 - Reasons given for disapproval

Survey assessment of quality of review



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Assessment of board observation

- Read protocol/ documents before board observation
- Make your own assessment about technical and ethical issues
- Listen to analysis by board members
- Take note of good comments and procedures
- Take note of deficiencies
- Fill up board observation form
- Discuss during summary meeting

Outcome of Board Observations

- Assessment of quality of review
 - Actual review practices
 - Comprehensive review points
 - Competent decision making
 - Good suggestions to PI to improve protocol, ICF, etc.
- Competence of EC members and staff
- Complete procedures (including post review procedures)

Meeting review

- [SIDCER-FERCAP Form 016 - Board Meeting Observation Checklist version 02102016.docx](#)

Protocol File Review

- Contains the history of the protocol from the time of submission to final report
- Adequate and timely documentation in the protocol file
- Review forms and checklists are filled up properly
- Timelines are followed

Protocol review

- [SIDCER-FERCAP Form 013A - Quality of Protocol Review Checklist version 08102014.docx](#)
- [SIDCER-FERCAP Form 013B - Quality of Continuing Review Checklist version 02102016.docx](#)

Protocol review

- [SIDCER-FERCAP Form 012 - Protocol File Review Checklist version 08102014.docx](#)

Minutes

- Contain all relevant protocol/ document details
- Discussion points
- Decision
- Quorum
- COI
- Approved during the next meeting
- Signed

- SIDCER-FERCAP Form 014 - Meeting Minutes Review Checklist version 02102016.docx

Any Questions... Just Ask!

