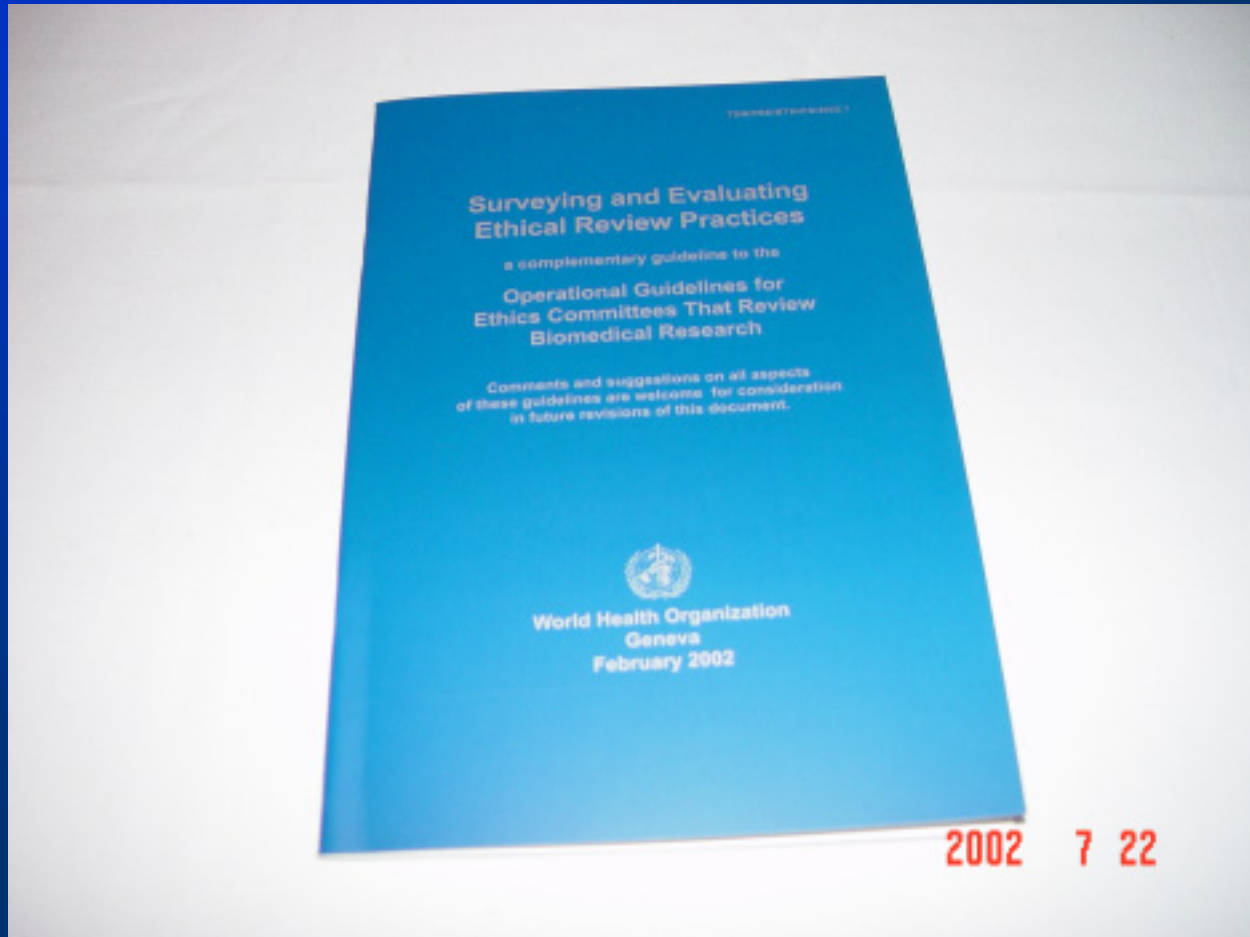


IRB Surveying and Evaluation

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Surveying & Evaluating Ethical Review Practice



Guideline: Surveying & Evaluating Ethical Review Practice

- o aim: to facilitate and support procedures for assisting the development of **QUALITY** and **TRANSPARENCY** in ethical review
- o review and feedback on practices and performance of ethics committees vis-à-vis established standards of ethical review
- o allows for independent evaluation

Definition – Survey

- ◆ The activity of reviewing an ethics committee in order to analyse and evaluate its ethical review practices with a view toward quality improvement and transparency
- ◆ A survey may also be conducted of a human subject protection program, with a wider scope than just the ethics committee

Definition – Evaluation

- ◆ The assessment by an independent surveyor of the strong and weak points of an ethics committees' practices based on the findings of a survey

Overall Goals of Surveying and Evaluating Ethical Review Practices

- ◆ To review practices and appraise performance
- ◆ To develop the quality and transparency of ethical review
- ◆ To contribute to the education of ethics committees
- ◆ To increase public confidence in the ethical review of research

The Approach

- ◆ There should be a predefined framework, preferably established by government or other organization
- ◆ Absent a national framework, the institution or ethics committee establish the framework
- ◆ There should be open and frank discussion

SOPs for Surveying and Evaluating

It is useful to have written procedures for the activities, addressing all the requirements including:
















- ◆ Assignment of independent surveyors
- ◆ Conflicts of interest
- ◆ Confidentiality

Survey Plan

The independent surveyor should provide a survey plan in advance to the ethics committee

- **designed for each review activity**
- **drafted by surveyor**
- **communicated in advance to EC for agreement (3 weeks)**
- **designed in accordance with SOPs for surveying**

Survey Plan

-  **identification and location of surveyor**
-  **identification and location of EC and person representing EC**
-  **identification of persons to be interviewed**
-  **reason for the survey and evaluation**
-  **objective and scope of the survey and evaluation**
-  **expected time and duration for each major survey activity**
-  **date(s) and location of the survey**
-  **schedule and purpose of meeting to be held**
-  **language**
-  **confidentiality requirement and confidentiality statement**
-  **identification of reference documents to be used**
-  **documents of the EC to be reviewed**
-  **distribution of the report**
-  **foreseen follow-up actions to the survey**
-  **expected date of the survey and evaluation completion**

Preparation before the Survey

- Identify team member
- Distribute responsibility of evaluations to each member of the team
- Each member prepare his/her checklist for the responsible task
- Discuss agenda, timeframe, attitude, methodology

Attitude of evaluators

- Non-judgmental attitude
- Be a good listener
- Ask short, and open questions
- Keep yourself within the scope
- When see contradiction – look for evidence for confirmation i.e.- documentation

The method

- Interview EC member - the chairperson, secretary, other members.
- Ask questions to EC members
- Examine the documents-SOPs, protocols, minutes, reports of SAE, agendas, CV of EC members, history SOP, decision letters, etc

The Method

- Follow agenda
- Keep the timeline
- Stay within the scope
- Evaluation is based on documentation and facts
- Do not give answers even if they ask questions so that they can talk
- look for contradiction - confirmed by evidence i.e.documentation

The Conduct of Survey and Evaluation

Conduct according to a mutually agreed survey plan

- **Opening meeting**
- **Review of documentation**
 - EC's legal framework
 - Review of the EC membership
 - Review of the EC SOPs (*application, review procedure etc.*)
 - Review of the EC meeting conduct
 - Review of Protocols
- **Summary of findings and Survey observation**
- **Closing meeting**
- **The report**
- **The follow-up**
- **The final report**

The Conduct of Survey and Evaluation

- **Opening meeting**
- **Review of documentation**
 - ✓ EC's legal framework
 - ✓ Review of the EC membership
 - ✓ Review of the EC SOPs
 - ✓ Review of the EC meeting conduct
 - ✓ Review of Protocols
- **Summary of observation**
- **Closing meeting**
- **The report**
- **The follow-up**
- **The final report**

Opening meeting

- ◆ introduction
- ◆ purpose and scope
- ◆ agenda & survey plan
- ◆ survey methodology
- ◆ documents to be reviewed
- ◆ current practice of EC
- ◆ practical arrangement
- ◆ time and date for closing

The Conduct of Survey and Evaluation

- Opening meeting

- **Review of documentation**

- ✓ EC's legal framework
- ✓ Review of the EC membership
- ✓ Review of the EC SOPs
- ✓ Review of the EC meeting conduct
- ✓ Review of Protocols

- Summary of observation

- Closing meeting

- The report

- The follow-up

- The final report

Review of documents

- ◆ documents properly collated?
Clear Identification?
- ◆ carefully stored? Missing?
- ◆ sufficient and appropriate for the task
- ◆ meet requirement of regulations, guidelines, SOPs

The Conduct of Survey and Evaluation

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Review the legal framework

- ◆ Authority under which the EC is formed/establishment – under what authority is the EC established?
- ◆ Terms of reference of the EC – what are the terms of reference of the EC?
- ◆ Scope of authority – what is its scope of authority?
- ◆ Local legislation/international guidelines – what local and international guidelines does the EC follow?

The Conduct of Survey and Evaluation

- Opening meeting

- Review of documentation

- ✓ EC's legal framework
- ✓ **Review of the EC membership**
- ✓ Review of the EC SOPs
- ✓ Review of the EC meeting conduct
- ✓ Review of Protocols

- Summary of observation

- Closing meeting

- The report

- The follow-up

- The final report

Review the EC membership

- ◆ membership requirement
- ◆ Terms and procedure for appointment of EC member
- ◆ condition of appointment
- ◆ listing of current & previous
- ◆ CVs of current and previous
- ◆ requirement for EC offices
- ◆ responsibilities and duties of offices of EC
- ◆ quorum requirement

The Conduct of Survey and Evaluation

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 - ✓ Review of the EC membership
 - ✓ **Review of the EC SOPs**
 - ✓ Review of the EC meeting conduct
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Review the constitution of EC SOPs

- ◆ SOPs on SOPs
- ◆ creation/revision
- ◆ approval/implementation
- ◆ historical SOPs
- ◆ SOPs deviation

The Conduct of Survey and Evaluation

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 - ✓ **Review of the EC meeting conduct**
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Review the meeting conduct

- ◆ frequency
- ◆ agenda
- ◆ timeframe
- ◆ meeting procedures
- ◆ procedures for reviewing
- ◆ minutes/approval

The Conduct of Survey and Evaluation

- Opening meeting
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 - ✓ Review of the EC SOPs
 - ✓ Review of the EC meeting conduct
 - ✓ **Review of Protocols**
- Survey observation
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Review protocol

- ◆ elements of the review
- ◆ condition for expedite review
- ◆ decision-making procedures
- ◆ procedures for communicating decision
- ◆ minutes
- ◆ follow-up review (SAEs etc.)
- ◆ documentation & archiving

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Survey Observations

- ◆ findings must be documented
- ◆ review findings and present
- ◆ findings should be supported by evidence and reference made to relevant requirement
- ◆ follow-up review (SAEs etc.)
- ◆ documentation & archiving

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Closing Meeting

- ◆ Acknowledgement of IRB cooperation
- ◆ summary of areas surveyed
- ◆ guidelines/regulations being followed
- ◆ review of survey findings
- ◆ opportunity for EC to ask questions and comments
- ◆ any recommendation for actions required to be undertaken by EC and time period for their accomplishment

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- **The final report**

The Report

- ◆ well presented document, easy to understand, reflect the findings of survey, dated and signed by surveyor
- ◆ ID of surveyor, IRB & representatives
- ◆ purpose and scope of survey
- ◆ survey plan
- ◆ ID facilities, person interviewed and document reviewed
- ◆ finding of survey
- ◆ surveyor's evaluation
- ◆ recommendation of corrective action
- ◆ report distribution list

The Conduct of Survey and Evaluation

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The Follow-up

- ◆ Survey plan - prepared by surveyor for follow-up review and agreed by EC
- ◆ EC is responsible for determining, initiating and completing the actions required to address the findings presented in initial report.
- ◆ Timeframe: decided at the closing meeting

The Conduct of Survey and Evaluation

Opening meeting

Review of documentation

- ✓ EC's legal framework
- ✓ Review of the EC membership
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- ✓ Review of the EC meeting conduct
- ✓ Review of Protocols

Survey observation

Closing meeting

The report

The follow-up

The final report

The final Report

- ◆ Report contains final set of information and overall evaluation supported
- ◆ The final report should be communicated to the entity under which the survey and evaluation takes place, the EC, and others as defined within the framework of national law or as mutually agreed by the surveying entity and the EC

Summary:

- ◆ Legislation and basis (guidelines) to support their function to act as EC
- ◆ EC members – qualified; have time and commitment;
- ◆ Decision process – follows SOP; systematic; ensures adequate protection of subjects
- ◆ Reporting systems (i.e. SAE) ensure adequate protection of subjects
- ◆ SOPs written, adequate, followed, meets expected in approved, disseminated
- ◆ Protocol review

- ◆ Documentation (e.g. minutes of meetings, SOPs)

requirements are adequate (ensures protection of

**“The greatest challenge to any thinker
is stating the problem in a way that
will allow a solution.”**

- Bertrand Russell