

# Methods of Ethics Committee Review of Protocol

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# Outline

- Objective
- Message
- Quorum
- Submission of protocol
- sorting

# Outline

- Peer review
- Committee discussion
- Decision
- appeal
- Conclusion

# Objective

- To equip learners with the skill of approving protocol

# Message

- Appropriate steps required must be taken for authenticity of ethics committee's approval or disapproval of protocol

# Quorum

- Quorum must be formed before meeting commences
- At least one lay person must be on sit before commencement of meeting
- Minutes of last meeting read and adopted

# Quorum

- Matters arising from minutes taken
- List of protocols for discussion circulated
- Each member allocated a protocol for presentation

# Approaches

- Submission of protocol
- Sorting
  - Exempted review
  - Expedited review
  - Full committee review



# Approaches

- Peer review
- Revision of protocol
- Interaction with researcher
- Decision
- Appeal

# Submission of Protocol

- Protocols submitted in two duplicates
  - Application form
  - Payment of prescribed fee
  - Completed informed consent form

# Sorting

- Protocols sorted into
  - Exempted review
  - Expedited review
  - Full committee review

# Peer Review

- Protocol peer reviewed
  - Expert for science of the protocol
  - Ethicist for ethics of the protocol

# Peer Review

- Report to committee chair
- Research respond to queries (if any)
- Preparation for committee's consideration

# Researcher's Response

- Researcher responds to reviewers queries
  - Writing
  - Dialogue if further clarification required

# Exempted & Expedited Review

- Review done by committee chairperson or designated person
- Approval given by chairperson
- Committee notified for ratification
- Disapproval discussed by committee

# Full Committee Review

- Protocol listed for discussion
- A committee member presents protocol and seek approval
- Members discuss protocol
- Members vote



# Conflict of Interest

- Member with conflict of interest declares his/her interest
- Excused himself from discussion and decision on protocol
- Return to meeting after decision is made

# Decision

- Decision
  - Consensus
  - Vote
    - Abstain
    - Vote
    - Refusal to vote

# Decision

- Types of decision
  - Approval
  - Disapproval
  - Modification

# Decision

- Majority vote upholds as committee's decision

# Referral

- Ethics committee may refer cases to national Health Research Ethics Committee
  - Complain
  - Study has national outlook

# Referral

- Collaborate with other sister ethics committee
  - Study location

# Appeal

- Aggrieved applicants may protest within 90 days of decision
- Complain will be addressed

# Conclusion

- Ethics committee members have basic training in ethics
- Conflict of interest must be properly addressed
- Community interest uppermost in protocol review