

Procedure for Full Ethics Committee Meeting

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Submission of Protocol to Research Ethics Committee (REC)

- Provision of detailed information about the study by the lead investigator (PI)
- Submission is done using a REC developed protocol form and procedures
- Protocol submission and processing may be by deadlines or on “first come, first served” basis
- Follow established administrative process for proper documentation and acknowledgement

Materials for Submission

- Full protocol
- Institutional summary protocol and attachments
- Consent form
- Investigator brochure: for new drugs
- Recruitment materials: advertisement, posters, radio scripts, brochures, etc.
- Clinical trial agreements
- Interview questions, copies of surveys, etc.
- Others: ethics education certificate (CITI), REC fee, etc.

Pre-review & Distribution of Protocols

- Submitted applications are triaged into review categories
- Pre-review of protocols for full REC review is done either by administrative staff or by REC chair/designated REC member
- Assignment of primary and secondary reviewers taking note of expertise and potential conflicts of interests

Reviewer's Worksheet

- Introduction, aims, background and significance
- Drugs, devices and biologics
- Scientific design
- Research procedures
- Inclusion/exclusion criteria for participants
- Statistical analysis and data monitoring
- Participants privacy and confidentiality

Reviewer's Worksheet

- Recruitment of participants
- Compensation and costs to participants
- Potential risks/discomforts and benefits for participants
- Informed consent/assent
- Other issues e.g. allocation of resources, potential conflicts of interests, etc.

Pre-Meeting Administrative Tasks

- Collecting submission materials
- Pre-screening of protocols/continuing reviews
- Determine attendance for upcoming meeting
- Meeting logistics-location, catering, schedules with PIs, guests
- Assemble/distribute materials for review to REC members
 - agenda, minutes, summary of expedited reviews
 - new protocols, continuing renewals, etc.
 - adverse events, amendments
 - other items (educational materials, draft policies, etc.)
 - announcements

REC's Preparation for Meeting

- Conduct a systematic review of the protocol and application materials
- Clarify as many issues as possible before the meeting
- Decide if the investigator should attend the meeting

Discussion at REC Meeting

- Each REC should use the approach that fits best with the personalities and interpersonal styles of the committee
- Each REC should use a system that promotes an efficient discussion in an atmosphere that encourages all members to express their views

Discussion at REC Meeting

- First primary reviewer uses an organize format to summarize and discuss important issues in the protocol
- Second primary reviewer comments on the protocol
- Other assigned reviewers (if necessary) present their comments
- The chair opens up the discussion to the full committee
- Other routines may equally work well

Arriving at a Decision

In order for research to be approved, the decision shall ordinarily be arrived at by *discussion* and *consensus* or it shall receive the support of a *simple majority* of those members present at the meeting

The Voting Options

- Approved
- Minor revisions required
- Not approved
- Recuse
- Abstain

Post- Meeting Administrative Tasks

- Communicating meeting's decisions to researchers
- If appropriate, assists PIs in interpreting or responding to concerns
- Preparation of minutes
- Maintenance of research study materials
- Tracking studies e.g. electronic database

Resources & Further Readings

- National Code of Health Research Ethics, Federal Ministry of Health, Abuja, Nigeria, 2007
- Institutional Review Board: Management and Function by Elizabeth A. Bankert and Robert J. Amdur Chapter 5
- REC Administrator 101 (PRIM&R)