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Ethics Review Process in Health Research by NatREC

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Outline

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This presentation highlights on the following:

- The MRCC proposal format
- Ethical review and clearance process
- What reviewer look into when reviewing proposals
- Categorization of reviews
- Submission requirements

How should a proposal be structured?

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MRCC proposal format

- Summary
- Introduction and Literature review
- Statement of the problem
- Rationale
- Objectives
- Methodology (including data collection instruments)
- Ethical considerations
- Dissemination of research results
- Personnel CVs
- Work plan
- Budget and budget justification

Ethical Review and Clearance Process

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Three steps involved:

1. Application procedure
2. Review Process
3. Clearance Process

Step 1. Application Procedure

- Five (5) copies of the research proposal
- Submission letter by PI, **Appendices:** letter from Institutions (foreign & local), CVs, and Institutional ethical approval
- Filled in online application form
- Application fee (payable by Bank deposit)
- All to be submitted to the NatREC Secretariat at NIMR-Hqs

Step 2. Ethical review process

- Proposals are registered and sent to 3 primary reviewers.
- Reviewer reports received by secretariat within 3 weeks.
- Reviewer reports forwarded to PI.
- PI revises proposal within a month and resubmits to the NatREC secretariat.
- Proposal & review reports received and reviewed by the full committee meeting (held monthly).

Step 3. Ethical Clearance Process

- Approval is granted by Ethics Committee
- Secretariat prepares the certificate
- Signed by two signatories:
  - NIMR- Authority
  - MoHSW -Authority
- Certificates are obtained from NatREC secretariat office at NIMR
- Ethical Approval granted within 6 - 8wks.

(Approval is valid for one year)

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What do Reviewers look into when reviewing a proposal?

I. Scientific issues examined in the proposal

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- Objective of the study
- Rationale of the study
- Research methodology
- Knowledge on literature review
- Budget and budget justification
- CVs of investigators

II. Ethical issues examined in the proposal

- Social value
- Confidentiality measures
- Compensation for time and travel
- Informed consent
- Dissemination of results to key stakeholders

Clinical Trials Proposals

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- Clinical Trials (CT) proposals are reviewed by a sub-committee composed of experts in CT conduct.
- A report is then sent to NatREC for final decision.
- The CT subcommittee also reviews all reports generated from the approved CT projects e.g. Progress reports, Final reports and Server Adverse Event (SAE).

Clinical Trials cont…

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The following issues are also examined in a CT proposals:

- Investigator Brochure
- Insurance of Clinical Trials participants
- Information on registration of the drug/device through TFDA
- Phases of the clinical trial i.e. Phase I, II, III or IV
- Data Safety Management Board (DSMB)
- Follow up mechanisms for participants who wish to discontinue.

Categorization of Review decisions

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1. As presented

- If both the scientific and ethical issues have been well addressed by the PI.

Categorization cont....

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2. Minor revision

- No summary.
- Budget presented is not well justified.
- Compensation for participation is not well addressed.
- Study limitations not mentioned.
- Information leaflet to participants not attached.

Categorization cont...

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3. Major revision

- Ethical issues not considered
- No informed consent process/ IC form attached
- Inadequate Statement of the problem
- Objectives are not clear
- Methodology is not clear
- No data collection tools

Categorization cont...

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4. Not recommended / Rejected

- Researchers do not comply with ethical and country requirements.
- Researchers do not address the reviewer's and committee's comments.

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Requirements for submitting a proposal.

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- 5 copies of a complete proposal with filled in application form for Ethics approval.
- Informed consent & tools (English & Kiswahili).
- CVs of all investigators local & foreigners.
- Application fee pay slip (paid at the Bank)

For students

- Cover letter from academic institution.

For collaborative research

- Cover letter from local collaborator based in a specific institution in Tanzania.

2. Amendment

- Proof of original the approval
- Amended proposal stating changes made e.g.: - PI/Co investigator
    - Site
    - Sample size
    - revised Informed Consent form
    - e.t.c.

3. Renewal/ Continued/ Extension Reviews

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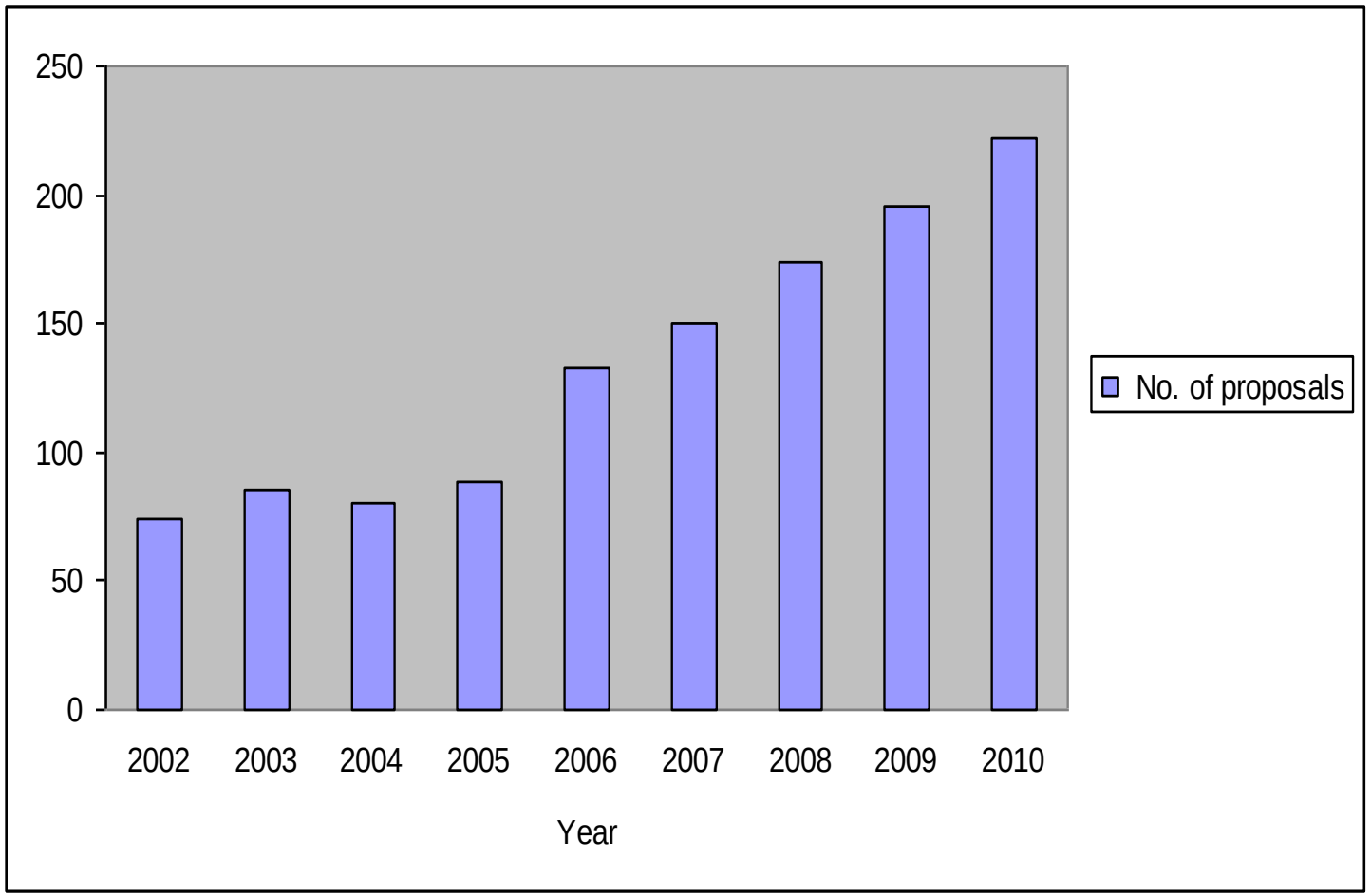
- Proof of original approval
- Progress report showing:
  - Activities achieved
  - Remaining activities to be done

Health Research proposals reviewed at NIMR



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Thank you for listening