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COLLEGE OF HEALTH SCIENCES
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KNH-UoN ERC
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KENYATTA NATIONAL HOSPITAL (KNH)
P O BOX 20723 Code 00202
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KNH–UoN ERC GUIDELINES FOR PROPOSAL DEVELOPMENT

1. Title
2. Principal Investigators, co-investigators and supervisors where applicable
   -Their addresses and signatures should be included.
   -Role of investigators/supervisors as applicable
   -The committee may require their curriculum vitae
3. Any collaborating institution(s)
4. Funding agency where applicable
   -Declaration of originality of study where applicable
5. List of abbreviations and acronyms
6. Operational definitions
7. Table of contents
8. Structured summary (Approximately 200-300 words).
9. Introduction/background
10. Literature review including conceptual/theoretical framework
11. Rationale/ Study justification
12. Study questions, hypothesis where applicable
13. Objectives/Aims
    a) Broad objective(s)/overall goals
    b) Specific objectives
    c) Secondary objectives if applicable
14. Methodology
    a) Study design
    b) Study area description
       -Specific study site
    c) Study population
       -Population characteristics
       -Definition of cases/controls if applicable
       -Inclusion/exclusion criteria
    d) Sample size determination and formula/computer programme used (Assumptions and reference)
    e) Sampling procedure/screening/selection of study participants
    f) Recruitment and consenting procedures
    g) Variables – dependent, independent, confounders where applicable

h) Data collection procedures (qualitative and quantitative data, field data collection instruments, laboratory procedures etc)
i) Materials – equipment, supplies etc
j) Training procedures where applicable
k) Quality assurance procedures

15. Ethical consideration-briefly explain the ethical issues that may be associated with the study and strategies to address them
16. Data management (data entry, cleaning, storage, security and quality assurance, statistical analysis plans etc)
17. Study results dissemination plan
18. Study limitations and how to minimize them
19. Study timeline/time frame
20. Study closure plan and procedure
21. References
    Use internationally accepted format e.g. Vancouver, Harvard, American psychological association (APA) e.t.c must maintain format consistency
22. Budget and budget justification;
    Consider coverage of such areas as Personnel, salaries and salary disbursements, Training Costs, Participants service costs, Supplies and equipment, Animal acquisition where Applicable, Travel and accommodation, Transport – vehicles – repair, fuel, operating expenses – postage, report writing e.t.c, Consultancy if applicable, Dissemination, Miscellaneous, Contingency (%)
23. Appendices for example:
    A) Informed Consent/assent explanation and consent form
        I) Consent explanation *(to include details on the following)*
            a) Title of study
            b) Investigators, their contacts and roles
            c) Study introduction,
            d) Purpose of the study
            e) Study procedures
            f) Role of the participant
            g) Type of specimens and amount to be obtained where applicable
            h) Possible storage of specimen for further analysis with the permission from the KNH-UoN ERC
            i) Follow up schedules if applicable/expected time in the study
            j) Benefits
            k) Risks and discomforts
            l) Confidentiality
            m) Study participants should consent for storage, transportation of their samples between laboratories and use of the samples for future research *(specific areas require consent)*
            n) Research related injuries and compensation (*where applicable*)
            o) Reimbursement mechanism
            p) Alternative treatments (*where applicable*)
            q) Voluntary participation
            r) Information on researchers and telephone numbers in case of any questions
            s) KNH-UoN ERC Secretary Contact telephone numbers 2726300 ext 44102, email uonknh_erc@uonbi.ac.ke
            t) Any other necessary information about the study

(Click here for consent explanation template)

II) Consent form to include investigators and participant statement with signature page;
(Click here for consent form template)
B). Study instruments/tools
C). Curriculum vitae where applicable
D). Reference procedures/ brochures etc where applicable
E). Maps where applicable
F). Special information e.g. educational/publicity materials
G). Any other relevant information according to the study

More information to researchers

1. Severe Adverse Events (SAE) should be reported to the KNH-UoN ERC within 72 hours as per the approved format ***(link to the SAEs form)***

2. Protocol violations/deviations should be reported to KNH-UON/ERC as soon as they occur. ***(Link to update form)***

3. KNH-UoN ERC approval is required for transfer of materials from one laboratory to another for analysis. ***(Link to transfer of materials form)***

4. The KNH-UoN ERC approval is given for one year only. The researcher is required to officially request for renewal at least 60 days to the expiry of the current approval and provide a detailed progress report for the preceding year. ***(Link to the updated form)***

5. KNH-UoN ERC will make study site visits as and when deemed necessary

6. The Principal investigator must provide the executive of the study summary and a list of publications to KNH-UON ERC of the at the end of study

7. The Principal investigator must provide study closure report if the study ceases to continue for whatever reason. ***(Link to the study closure application and policy form)***