NATIONAL HEALTH SCIENCES RESEARCH COMMITTEE

MINISTRY OF HEALTH
P.O. BOX 30377
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MALAWI

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FORM 101

APPLICATION TO CONDUCT HEALTH RESEARCH IN MALAWI

NHSRC INSTRUCTIONS AND GUIDELINES ON SUBMITTING A RESEARCH PROPOSAL

- **20 copies** of a completed application form.
- Registration fee of $150 or its equivalent in MK. Cheques payable to NHSRC.
- **20 copies** of the research **proposal summary** *(maximum 4pages)* and an **electronic version** as well.
- **20 copies** of Informcd consent form *(In both English and Chichewa or other local language)*
- **20 copies** of the full **research proposal** and an **electronic version** as well.
- **20 copies of CVs** for the PI and Co-Investigators.
- **10% Contribution fee** should be included in the budget

NHSRC

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NHSRC/A/.....

FC☐ EXP☐ XMPT☐

NHSRC FORM 101

Date received

.....

APPLICATION TO CONDUCT HEALTH RESEARCH IN MALAWI

This form must be completed by all persons/teams intending to conduct health research in Malawi. An application fee of $150 or its equivalent in Malawi Kwacha should accompany each application. Cheques should he made payable to the National Health Sciences Research Committee.

Protocol Version Number:.....

Details of Research Team

Name of Principal Investigator (P.I)	
Nationality of P.I	
Professional Qualifications	
Title	
Institution & Dept.	
Postal address	
E-mail address Fax No.	
Telephone No.	
Fax No.	
Is this research expected to lead to the award of a higher degree? (Yes/No)	
If Yes, name the University/Institution where registered	

Co-investigators Names	**Qualifications**	**Institution/Department**

Details of the Proposed Research

Title of study.	
Proposed starting date	
Proposed ending date	
Study site(s) in Malawi	
Study sites (outside Malawi)	
Budget (state currency)	
Name and address of Funding agency:	
Name of Sponsor	
Postal address	
E-mail address	
Telephone No.	
Fax No.	
Status of funding :	a)Submitted for funding ☐ b)Pending ☐ c)Funded☐

Collaborating/Affiliating Institutions

All foreign researchers need to be affiliated to local institutions

1st	
2nd	
3rd	

Methodology

Type of Study (Design)
(tick all that applies)

Survey	: ☐
Secondary data	: ☐
Program Project	: ☐
Clinical community trial	: ☐
Case control	: ☐
Longitudinal study	: ☐
Record review	: ☐
Course activity	: ☐
Other (specify)	:.....

Population
(tick all that apply)

Males	:☐
Females	:☐
Adolescents (12- 17 years)	:☐
Children (Under 12 years of age)	:☐
Pregnant women	:☐
Foetuses	:☐
Elderly (over 65 years)	:☐
Prisoners	:☐
Cognitively impaired	:☐
Hospital inpatients	:☐

Sample

Sample size

Data Collection Methods

Interviews	:☐
Observation	:☐
Focus Group Discussion	:☐
Experience	:☐
Other (Specify)	:☐

Determination of Risk (*tick all that applies*)

Does the research involve any of the following	YES	NO
Human exposure to ionizing radiation	☐	☐
Fetal tissue or abortus	☐	☐
Investigational new drug	☐	☐
Investigational new device	☐	☐
Existing data available via public archives/sources	☐	☐
Existing data not available via public archives	☐	☐
Observation of public behavior	☐	☐
Is the information going to be recorded in such a way that subjects can be identified	☐	☐
Does the research deal with sensitive aspects of the subjects behaviour, sexual behavior, alcohol use or illegal conduct such as drug use	☐	☐
Could the information recorded about the individual if it became known outside of the research, place the subject at risk of criminal prosecution or civil liability	☐	☐
Could the information recorded about the individual if it became known outside of the research, damage the subject's financial standing, reputation and employability?	☐	☐

- **Do you consider the proposed research**
  - (a) greater than minimal risk ☐
  - (b) minimal risk ☐
  - (c) no risk ☐

Minimal risk is a risk where the probability and magnitude of harm or discomfort anticipated in the proposed research are not greater in and of themselves than those ordinarily encountered in daily life or during the performance of routine physical, psychological examinations or tests. For example the risk of drawing a small amount of blood from a healthy individual for research purposes is no greater than the risk of doing so as part of routine physical examinations.

Ethical Considerations

Consent Process (*tick all that applies*)

Written :☐ Oral :☐

Language

English :☐ Local Language :☐ Other (Specify) :☐

Conflict of Interest

- Does any of the participating investigators and or their immediate families have an equity relationship with the sponsor of the project or the manufacturer or owner of the drug or device under investigation or serve as a consultant to any of the above?

  YES ☐ NO ☐
  If yes, ***please submit a written statement of disclosure to the Chairperson of the NHSRC***

A research protocol summary *(4 pages maximum)* should state the following:

1. **RESEARCH QUESTION TO BE ADDRESSED BY THIS PROPOSAL**

2. **RATIONALE FOR RESEARCH**
   - Describe briefly the background of the study, and state reasons for conducting it.
   - Stale objectives of study.

3. **METHODS**
   - Study design and rationale for that design. Explain how the study will be performed.
   - Population : Sample size, outline criteria for selection and exclusion of subjects, gender, ethnic group, performance sites (provide justification for single gender or group). For larger sample sizes on greater than minimal risk studies, provide justification of the sample size.
   - Subject's state of physical health. Indicate if healthy, i11, seriously ill or terminally i11.
   - Does the study involve any special populations: Subjects will include, minors, fetuses, abort uses, pregnant women, prisoners,
     mentally retarded, mentally disabled, or none of the above.
   - If subjects arc from one of the above special populations explain the necessity for including them.
   - Specify source of participating subjects, e.g. hospitals, clinics, institutions, prisons, industry, unions, schools, general population, etc.
     NOTE: If you plan to advertise for patients, the ad must be submitted to the NHSRC for review and approval prior to its publication
     and/or posting.
   - List all research procedures and/or interventions involving human subjects (when applicable) including tests to be conducted and the
     analysis of samples (where applicable including where the analysis is to be done – if outside the country please justify including how the samples are to be shipped).
   - Distinguish procedures which are part of routine care from those that are part of the study
   - Questionnaire/interview instrument (when applicable)
     If the study includes either of these, a copy of the instrument is to be appended to this application. If the instrument is in development stages, provide an outline of the types of questions to be asked and the expected date of completion and submission to the NHSRC.
   - Methods of intervention Will any new drugs or biologic agents be administered to the subjects, or will previously used agents be used in a new manner? If **yes**, please note that you are also required to file a separate application with the Medicines Control Authority of Malawi (PMB) and may not conduct your study without the approval of both the PMB and the NHSRC. You are also required to complete
     the relevant part in this application titled "Studies involving the testing of drugs and medical devices".
   - Methods for dealing with adverse events
   - Methods for dealing with illegal, reportable activities (e.g. child abuse)

4 **RISKS / BENEFITS TO SUBJECTS**
   - Describe in detail any potential risks - physical, psychological, social, legal, ethical (e.g. confidentiality), or other and assess the likelihood and seriousness of such risks (none, low, moderate, and high). Include the incidence of complications if known. You may use a narrative description if more appropriate or a table with 3 columns (Potential adverse effects, seriousness and likelihood of complications (Incidence if known.)
   - Describe procedures for protecting against or minimizing potential risks.
   - If the activity involves women who could become pregnant and is potentially harmful to a fetus, describe steps that will be taken to prevent pregnancy or exclude pregnant women.
   - Assess potential benefits to be gained by the individual subject and explain why the benefits outweigh the risks.
   - Assess benefits which may accrue to society in general as a result of the planned work**.**

5. **COSTS AND COMPENSATION**
   - Will subjects receive compensation, monetary or other? If monetary, how much? Will subjects be asked to assume any out-of-pocket costs for participating in the research? If yes, what? Identify expenses such as additional transportation, laboratory tests, supplies, cost of study drug if it becomes commercially available, etc.

6. **CONFIDENTIALITY ASSURANCES**
   Describe any means by which the subject's personal privacy is to be protected and confidentiality of data maintained. Include information on the following:
   - Any sensitive information that will be gathered**.**

- Plans for record keeping
- Location of the data
- Data security
- Person responsible and telephone number
- Who will have access to the data
- Plans for disposal of the data upon completion of the study

7. **CONFLICT OF INTEREST (real or apparent)**

- Other than the normal scholarly gains, are there any other gains you might receive from taking part in this study?

8. **COLLABORATIVE AGREEMENTS**

- Provide letters of approval from collaborating institutions' IRBs and from other local IRBs from other sites.

9. **INTENDED USE OF RESULTS**

- Include plans for dissemination and utilization of study results

OTHER INFORMATION:

- Any other information.

FULL RESEARCH PROPOSAL

Attach 20 HARD COPIES of the full research proposal and an electronic copy. The full proposal should include the following: Title, objectives, background and literature review, methodology (to include research design, subjects and methods, ethical considerations, work plan etc. references, budget etc (Please refer to the Checklist). Investigators may submit the full proposal in the funding agency format as long as it covers the above headings.

Please also attach copies of **curriculum vitae** for the Principal Investigators and all Co-investigators. The CVs should include the following: Name, Postal address, Employers name and address, email, fax number, Qualifications, Present Position, Past research experience (relevant) and Published Papers (relevant). Principal Investigators or co-investigators who would have already submitted their CVs during the last two years are exempted from this requirement.

INFORMED CONSENT *(**English*** and Chichewa ***or any other appropriate local language)***

- *Any kind of contact with human subjects requires a disclosure/consent process.*
- *Attach a copy of the consent form. Indicate how (verbal or written) informed consent will be obtained*
  (please request for guidelines for implementing informed consent from the NHSRC Secretariat).
- *If subjects are minors or mentally disabled, describe how and by whom permission will be granted.*
- *Where will the record of consent be stored? (Consent forms must be kept for three years after the*
  completion of the investigation, unless otherwise stipulated by the NHSRC).

STUDIES INVOLVING THE TESTING OF NEW INVESTIGATIONAL PRODUCT

INVESTIGATIONS, PRODUCT INFORMATION FORM

Please note that you are required to submit a separate application to the Pharmacy, Medicines and Poisons Board.

1. Which of the following will be used?

- ☐ a) investigational drug(s)
- ☐ b) new therapeutic applications for PMB approved drug (s)
- ☐ c) new combination of any of the above
- ☐ d) medica device
- ☐ e) Any other (Specify)

2. Briefly describe how this investigational product is a part of the proposed study.

3. For each investigational product to be used, please provide the following information:

Generic Name	Trade or Brand Name	Manufacturer
_____	_____	_____

4. Please give the risks, hazards, known contraindications.

5. Please provide dose schedule, route of administration, and duration of therapy.

SIGNATURE ASSURANCE SHEET

Principal Investigator's Assurance Statement:

I certify that the information given by me is correct to the best of my knowledge, I am familiar with and understand the NHSRC's policy concerning research involving human subjects international guidelines and I agree:

(Please tick all that applies)

1. ☐To accept responsibility for the scientific and ethical conduct of this research study;

2. ☐To obtain prior approval from any other IRB as well as the NHSRC before amending or altering the
research protocol or implementing changes in the approved consent form;

3. ☐To immediately report to any other and the NHSRC any serious adverse reactions and/or unanticipated effects on subjects which may occur as a result of this study;
4. ☐TO complete and submit the Continuing Annual Review Form
5. Final/Study termination form at the end of the proposed study using a standard form.
6. ☐To submit the final study report to the NHSRC.
7. ☐To pay $150 application fee or its equivalent and 10% contribution fee of the total budget to the NHSRC (for institutional capacity strengthening and operations).
8. Please complete the NHSRC Checklist before submission.

Signature _____ Date _____

Print name _____

Signature of Co-investigator _____ Date _____

Print Name _____

For further details, refer to the NHSRC guidelines.

SUBMIT TWENTY COPIES OF THE ENTIRE APPLICATION PROPOSAL TO THE NHSRC SECRETARIAT (The entire application package includes the checklist, application form, research proposal summary (4 pages maximum), full research proposal (In NHSRC format), consent form and other relevant documents).

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INSTITUTIONAL ENDORSEMENT REQUIRED

Statement from the Institution:

The NHSRC will only accept for review and approval research proposals that have been found scientifically acceptable by our institution. The acceptable Institutional endorsement will be that from the Institution in which the research is to be conducted or one from the institution conducting the research.

We, representing

.....
(Name of Institution conducting the research/in which the research is to be conducted)

do certify that we have reviewed the research proposal titled

.....

.....

Submitted by

.....

We attest to the scientific merit of this study and the competency of the investigator(s) to conduct the project and do hereby recommend the proposal to the NHSRC for review and approval.

SIGNATURES

Signature Date

Institutional representative _____ _____

Name (Please Print)

Signature: Head of Institution _____ _____

(or other authorized signatory)

Name (Please Print) _____

***Contact Number* :.....**

***E-mail address* :.....**

OFFICIAL STAMP OF INSTITUTION

Institution includes Universities, Hospitals, Research institutes or Companies.