NATIONAL HEALTH SCIENCES RESEARCH COMMITTEE

FORM 11-01

APPLICATION FOR CONTINUING REVIEW

STATEMENT OF POLICY

It is the policy of the National Research Council of Malawi (NRCM) and affiliated Institutional Ethical Review Committees (IERCs) that in the continuing review of ongoing research, the entire study will be reviewed to ensure the continued protection of the rights and welfare of the human participants. The NHSRC follows, at minimum, the regulations set forth in the Helsinki Declaration and CIOMS Guidelines as the criteria for continuing review. The Continuing Review process must be no less stringent than the initial review.

The Principal Investigator is responsible for timely submission of a continuing review application to prevent any lapse in NHSRC approval. NHSRC regulations do not provide for exceptions to the requirement for continuing review. Therefore, failure by the Principal Investigator to ensure timely review is a serious matter that may lead to suspension or termination of the study. **NO EXTENSIONS CAN BE GRANTED.**

If applying for **re-approval for long-term follow-up or data analysis only**, complete sections A, C,D,E, F, and H only.

A. STUDY INFORMATION			
NHSRC Protocol #		Expiration date of current approval period:	
Project Title:			
Principal Investigator :			
Institution:			

Phone:		Email:	
Contact Person: (If applicable)			
Role on Project:			
Phone:		Email:	

B. PROJECT FUNDING			
Funding:	☐ Unfunded		
	☐ Funded		
	Agency/Company Name:		
Payment of 10% fee to NHSRC:	☐ Pending	☐ Paid	☐ Planned

C. PERFORMANCE SITE(S)

List all performance sites for this study (including names of foreign countries with sites).

D. STATUS OF STUDY (check one)

Active study

☐ Recruitment/enrolment continues
☐ Accrual complete, research intervention continues
☐ Long-term follow-up
☐ Data analysis only, data collection complete

E. INTERVENTION INFORMATION

Intervention:

☐ Drug ☐ Device ☐ Genetic study ☐ Tissues

☐ Survey/Questionnaire ☐ Radiation Use ☐ Medical Record Review

☐ Other, Briefly explain

Drug/Device name:

F. PROGRESS REPORT

1. Enrolment and demographic information: LEAVE NO LINE BLANK

Total number of participants requested in original NHSRC application:

Number of participants enrolled since last progress report:

Total number of participants enrolled since the start of the study

Please report the number of participants in Malawi in the following categories: (Numbers must add up and make sense. Please check before submitting form)

	Currently active in study		Withdrawn from study
	Follow-up data collection only		Deaths related to study
	Completed intervention and any follow-up		Deaths unrelated to study
	Lost to follow-up		

2. Adverse Events, Complications, Study Withdrawals:

In the past approval period, did any participants suffer an unanticipated or serious adverse event or death? ☐ Yes ☐ No

If yes, please attach the Adverse Event Report(s) if adverse events not already reported to NHSRC.

Adverse events/overall risk: **Answer every question**.
Based on your knowledge of the adverse events for this study, do you feel that there is a significant increase in risks to participants? Has anything occurred since the last NHSRC & IERC review that may have altered the risk/benefit relationship? Explain.

Did you withdraw any participant(s) from your study because of a problem or complication? Explain.

Did any participant (s) withdraw themselves from your study? Explain .

Did any problems occur in obtaining or documenting informed consent (i.e., problems with subject understanding, high refusal rate, etc.) Explain.

NOTE: Attach a report of the Data Safety Monitoring Board if available. If not available, indicate when it is going to be available

3. Progress Report:

Please attach a brief summary of findings (preliminary or final) obtained in the study, a summary of recent literature or relevant information, especially information about risks associated with the study. Begin with a 1-2 sentence description of the purpose of the study. **If there are no findings at this time, this should be stated and explained.**

NOTE : Attach a report of the Data Safety Monitoring Board if available. If not available, indicate when it is going to be available

G. AMENDMENT / REVISION REQUEST Complete **ONLY** if Amendments or Revisions were requested.

HIGHLIGHT CHANGES TO THE REVISED CONSENT FORM WITH A BRIGHT COLOURED HIGHLIGHTER.

Approved Amendment(s): List the approved Amendments and briefly describe the nature of the approved changes and their rationale. Please attach an amended version of the protocol and/or the Informed Consent if applicable.

Human Participant Population: Has the human subject population changed? If yes, explain. Indicate if there are new performance sites or any changes in selection criteria.

Risks/Benefits: Describe if and how the risks/benefits have changed.

Principal Investigator's Assurance Statement:

I understand NCST 's policy concerning research involving human participants and I agree:

1. to accept responsibility for the scientific and ethical conduct of this research study,
2. to obtain prior approval from the NHSRC before amending or altering the research protocol or implementing changes in the approved consent form,
3. to immediately report to the NHSRC any serious adverse reactions and/or unanticipated effects on participants which may occur as a result of this study,
4. to train study personnel in the proper conduct of human participants research,
5. to complete the Continuing Review and Final Report Forms.

Signature of Principal Investigator Date

Write/Typed Name of Principal Investigator

H. APPLICATION ENCLOSURES CHECKLIST

Check all that are included in your submission for continuing review.

The following **must be included** in the submission for continuing review:

☐ Continuing Review Application, complete with signature of PI
☐ Progress Report, attached to application
☐ Current copy of Consent Form(s)
☐ Copy of previous approval letter

Include the following only **if applicable**:

☐ Clean copy of Consent Form(s) with revisions if necessary (for new approval stamp)
☐ Informational letters used in place of consent form (cover memo)
☐ Adverse Event Summary Table
☐ Current Approval letters from other foreign sites with IERC
☐ Complete protocol including modifications previously approved by the IERC (if submitting an amendment or modification to original protocol)
☐ Recruitment Information (Ads, Web postings, letters etc., if modified from originally approved recruitment materials)
☐ Additional information PI considers important for review by NHSRC

This section is for NHSRC Use only

Comments :

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Decision :

_____

Chairperson's Signature : _____

Date----------