GOVERNMENT NOTICE NO. 36

SCIENCE AND TECHNOLOGY ACT

(CAP. 30:10)

SCIENCE AND TECHNOLOGY (PRESCRIBED ACTIVITIES) ORDER, 2026

IN EXERCISE of the powers conferred by section 38 of the Science and Technology Act, the National Commission for Science and Technology make the following Order—

Citation

1. This Order may be cited as the Science and Technology (Prescribed Activities) Order, 2026.

Prescribed activities

2. An activity listed in the *Schedule* shall not be carried out, except under the authority of a licence issued by the Commission.

Revocation G.N. 44/2024

3. The Science and Technology (Prescribed Activities) Order, 2024 is hereby revoked.

SCHEDULE (para. 2)

LIST OF PRESCRIBED ACTIVITIES

1. Research studies involving access, collection and transfer of plant and animal genetic material for research.
2. Research studies involving humans in the biomedical sciences.
3. Research studies in the social sciences and humanities.
4. Research studies in biotechnology.
5. Research studies involving genome editing in plants and animals.
6. Research studies in nuclear sciences.
7. Establishment of an institutional research ethics committee for clearing research involving humans.
8. Establishment of an institutional research ethics committee for clearing research involving animals.
9. Collection, storage, transfer and use of human samples for research.
10. Establishment of a technology transfer office.

Made this 23rd day of April, 2026.

H. NYASULU
Chairperson

(REF.: NO. NCST/RTT/1/20)

GOVERNMENT NOTICE NO. 37

SCIENCE AND TECHNOLOGY ACT

(CAP. 30:10)

SCIENCE AND TECHNOLOGY (LICENSING OF PRESCRIBED ACTIVITIES) REGULATIONS, 2026

IN EXERCISE of the powers conferred by section 50 of the Science and Technology Act, I, BRIGHT MSAKA, SC, Minister of Education, Science and Technology, on the advice of the Commission, make the following Regulations—

Citation

1. These Regulations may be cited as the Science and Technology (Licensing of Prescribed Activities) Regulations, 2026.

Interpretation

2. In these Regulations, unless the context otherwise requires—

"prescribed activity" means an activity prescribed by the Commission in accordance with section 38 of the Act".

Application and issuance of a licence

3.—(1) A person shall not engage in a prescribed activity, unless the person holds a valid licence issued by the Commission.

(2) A person who wishes to engage in a prescribed activity shall make an application to the Commission in the appropriate Form set out in the *First Schedule* and the application shall be accompanied by an appropriate fee as set out in the *Second Schedule*.

(3) The Commission may, upon consideration of the application made under subregulation (1)—

(*a*) approve the application and issue to the applicant a licence in Form N set out in the *First Schedule*; or

(*b*) reject the application and give the applicant reasons for the rejection.

(4) In the case of an application for—

(*a*) the conduct of research studies in biomedical sciences, social sciences, humanities, and biotechnology that involve human and animal subjects;

(*b*) the establishment of an institutional research ethics committee;

(*c*) studies in nuclear science and genome editing; and

(*d*) the establishment of a technology transfer office,

the Commission shall issue a licence to the applicant upon payment of a licence fee and a compliance and capacity building fee set out in the *Second Schedule*.

(5) The Commission may reject an application for a licence if the—

(*a*) application contains information which is misleading, erroneous, deceptive or likely to deceive;

(*b*) applicant does not meet the conditions required under the Act; or

(*c*) for any other reasonable grounds which the Commission deems appropriate.

(6) The Commission shall, within thirty days of receipt of a complete application to engage in a prescribed activity, communicate the outcome of the application to the applicant.

(7) A licence issued under subregulation (3)(*a*) shall be—

(*a*) non-transferrable; and

(*b*) valid for the period specified therein.

(8) Where the Commission rejects an application in accordance with subregulation (4)(*b*), the applicant may, at any time, re-apply for a licence upon addressing the shortfalls contained in the communication from the Commission.

Renewal of a licence

4.—(1) A licensee may, before expiry of the licence, apply to the Commission for renewal of the licence.

(2) An application for renewal of a licence shall be—

(*a*) in the appropriate Form set out in the *First Schedule*;

(*b*) made at least sixty days before the expiry of the licence; and

(*c*) accompanied by an appropriate fee set out in the *Second Schedule*.

(3) The Commission shall, in determining an application for renewal of a licence—

(*a*) take into account the compliance record of the applicant with the provisions of the Act, during the validity period of the licence; and

(*b*) consider the level of adherence of the licensee to the conditions set forth for the licence.

(4) Where, during the validity period of the licence, the licensee contravened the provisions of the Act, the Commission may—

(*a*) reject the application for renewal of the licence; or

(*b*) renew the licence, subject to such conditions as the Commission may determine appropriate.

Variation of a licence

5. The Commission may, on application by a licensee, vary the conditions of a licence in accordance with section 43 of the Act.

Suspension and revocation of a licence

6.—(1) The Commission may suspend or revoke a licence issued under these Regulations where—

(*a*) the licence was issued as a result of misleading or false representations made by the applicant;

(*b*) the licensee contravenes any of the conditions imposed on the licence; or

(*c*) for any other reasonable grounds which the Commission deems appropriate.

(2) The Commission shall, prior to suspending or revoking a licence, give an opportunity to the licensee to show cause why the licence should not be suspended or revoked, as the case may be.

Register of licensees

7.—(1) The Commission shall keep and maintain a register of licensees in Form O set out in the *First Schedule*.

(2) The register shall be available for inspection by members of the public during normal working hours.

Appeals

8. Any person aggrieved by the decision of the Commission under these Regulations may appeal the decision in accordance with Part IX of the Act.

FIRST SCHEDULE (reg. 3(2), 3(3)(*a*), 4(2)(*a*)

FORM A (reg. 3(2), (4(2))

APPLICATION FOR AUTHORIZATION TO CARRY OUT RESEARCH IN MALAWI REQUIRING ACCESS AND COLLECTION OF GENETIC RESOURCES

APPLICATION REFERENCE NUMBER_____

(*for official use)*

SECTION A

(*To be filled by the Applicant*)

Note: This application form is not for the purpose of exportation of genetic resources

1. Name of the Applicant _____

   Profession _____

   Address _____

   _____

   _____

   Tel: _____ Fax: _____

   E-mail _____ Website _____

2. Name of the institution to which the applicant is affiliated

   _____

   _____

Address _____

_____

_____

Tel: _____ Fax: _____

E-mail _____ Website _____

3. Name of the collaborator _____

Qualification and area of expertize _____

_____

_____

Address _____

_____

_____

Tel: _____ Fax: _____

E-mail _____ Website _____

4. Name of the institution to which the collaborator is affiliated

_____

_____

_____

Address _____

_____

_____

Tel: _____ Fax: _____

E-mail _____ Website _____

5. What type of agreement is there between the collector (*foreign researcher*) and a collaborator (*attach evidence*)

Memorandum of Understanding	Contract	other agreements (*specify*)

6. Type of materials to be collected

Common and local names	*Scientific name*	*Family*	*Order*	*Quantity*	*Part(s) of Material to be collected e.g. roots, leaves*	*Collection Site (s)*

7. Purpose of collections (*Tick where applicable*)—
   (*a*) Research
   (*b*) Propagation
   (*c*) Teaching
   (*d*) Export
   (*e*) Other(s) (*Specify*)

   _____

   _____

8. State the importance and relevance of the proposed study/work to Malawi.

   _____

   _____

   _____

9. Where will the list and duplicate collections be deposited?

   _____

   _____

10. Summary of collection method and equipment to be used.

    _____

    _____

    _____

11. Proposed collection dates _____

12. If the material is going to be exported, explain why?

    _____

    _____

    _____

13. Signatures :_____ Applicant
_____ Collaborator

SECTION B

(*To be filled by the Certifying Institution*)

14. Type of materials to be collected (Append copy of request)—
    (*a*) Botanical
    (*b*) Zoological
    (*c*) Others (*specify*)

15. State the importance and relevance of the proposed work to Malawi .

_____

_____

_____

16 Has any similar work been done in Malawi? If so explain.

_____

_____

_____

17. Conservation Status of Requested Materials (Tick where applicable)

Species name		*Type*		*Conservation Status*				
Common and local	*Scientific*	*Family*	*order*	*Endangered*	*Vulnerable*	*Rare*	*1 Endemic*	*Inter-Mediate*

18. Recommendations of the Certifying Institution.

_____

_____

_____

19. Name of the Certifying Institution.

_____

_____

20. Name of the Certifying Officer _____

21 Title of the Certifying Officer _____

Address _____

_____

_____

Tel: _____ Fax: _____

E-mail _____ Website _____

Signature of the Certifying Officer _____

(*Official stamp*)

SECTION C

[*To be filled by the Chairperson of the National Committee on Agriculture and Natural Sciences.*]

22. Application of_____to carry out research requiring access and collection of _____

_____

materials has been:

(*a*) Decision (*Recommended for approval / rejected*) _____

(*b*) Reasons (*If rejected*) _____

_____

_____

23. Name of the Chairperson _____

Address _____

_____

_____

Tel: _____ Fax: _____

E-mail _____ Website _____

Signature and Date _____

SECTION D

[*To be filled by Director General of National Commission for Science and Technology*]

24. Application of_____to carry out research requiring access and collection of _____

_____

materials has been:

(*a*) Decision (*Recommended for approval / rejected*) _____

(*b*) Reasons (*If rejected*) _____

_____

_____

(*c*) Application reference _____

25. Name of the Approving Officer _____

26. Title of the Approving Officer _____

Address _____

_____

_____

Tel: _____ Fax: _____

E-mail _____ Website _____

Signature of the Certifying Officer _____

(*Official stamp*)

FORM B (reg. 3(2), (4(2))

APPLICATION FOR APPROVAL OF RESEARCH INVOLVING HUMANS IN THE BIOMEDICAL SCIENCES

Details of Research Team

Name of Principal Investigator (P.I)	
Nationality of P.I	
Professional Qualifications	
Title (Mr, Mrs, Ms, Dr, Prof. Rev etc.)	
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 ☐

National Health Research Agenda (NHRA) Monitoring

Thematic Area(s) addressed by the study (*Tick where applicable*)

Communicable diseases	
Non-communicable diseases	
Sexual and Reproductive Health	
Trauma	
Mental Health	
Environmental Health	
Nutrition	
Community System Strengthening	
Health Systems	

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

Data Collection Methods		Data Collection Tools (*In both English and local language*)	
Interviews	: ☐	Questionnaire/ Interview Guide:	☐
Observation	: ☐	Checklist	: ☐
Focus Group Discussion	: ☐	Focus Group Discussion Guide:	☐
Experience	: ☐	Experience	: ☐
Other (*Specify*)	: ☐	Other (*Specify*)	: ☐

Determination of Risk (*tick all that applies*)

	YES	NO
Does the research involve any of the following		
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

RESEARCH PROPOSAL SUMMARY

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.
   - State 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, ill, seriously ill or terminally ill.
   - 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 are 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 Pharmacy and Medicines Regulatory Authority of Malawi (PMRA) and Research Ethics Committee as registered by the Commission. 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 any 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 3 HARD COPIES of the full research proposal and an electronic copy. The full proposal should include the following: Title, background, objectives, literature review, methodology (to include research design, subjects and methods, ethical considerations, work plan, budget and references. (Please refer to the Checklist). Researchers 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 *curriculum vitae* should include the following: Name, Postal address, Employer's 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 *curriculum vitae* 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 research consent form. Indicate how (verbal or written) informed consent will be obtained from research participants*
- *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

INVESTIGATIONAL PRODUCT INFORMATION FORM

Please note that you are required to submit a separate application to the Pharmacy and Medicines Regulatory Authority

1. Which of the following will be used?
   - ☐ (*a*) investigational drug(s)
   - ☐ (*b*) new therapeutic applications for drug(s) approved by the Pharmacy and Medicines Regulatory Authority
   - ☐ (*c*) new combination of any of the above
   - ☐ (*d*) medical 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 Commission's policy concerning research involving human subjects 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 ethics approval from the biomedical research ethics committee registered by the Commission before amending or altering the research protocol or implementing changes in the approved consent form;
3. ☐ To immediately report to Commission and biomedical research ethics registered by Commission any serious adverse reactions and/or unanticipated effects on subjects which may occur as a result of this study whereas the research ethics is the one that gave ethics approval
4. ☐ To complete and submit the continuing annual review Form, if study goes beyond one year
5. ☐ Final/Study termination notification at the end of the proposed study
6. To submit the final study report to Commission.
7. ☐ To pay USD150 application fee or its equivalent and compliance and capacity building fee for human subjects protection activities being 10% of the total budget as indicated in the proposal on the issuance of the licence (i.e approval) of the research study
8. ☐ To clearly explain capacity building plans and roles for local collaborators involved in this study where applicable

Signature of the Principal Investigator _____ Date _____

Print name _____

Signature of Co-investigator _____ Date _____

Print Name _____

Signature of Co-investigator _____ Date _____

Print Name _____

INSTITUTIONAL ENDORSEMENT REQUIRED

Statement from the Institution:

The NHSRC will only accept for review and approval research proposals that have been found scientifically and ethically 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 research ethics committee of Commission for review and approval under a licence.

SIGNATURE

Signature: Head of Institution

(*or other authorized signatory*)

Name (Please Print) : .....

Contact Number : .....

E-mail address : .....

OFFICIAL STAMP OF INSTITUTION

*Note: please attach the following documents—

(*a*) 3 copies of Letter of Introduction (cover letter).

(*b*) 3 copies of completed application form.

(*c*) 3 copies of Research Proposal Summary (maximum 4 pages).

(*d*) 3 copies of Full Research Proposal including Implementation *Schedule* (Work plan), Itemized Budget (with 10% Compliance and Capacity building fee (for Human Subject Protection) included in the budget) and References.

(*e*) 3 copies of Participant Information Sheet (PIS) or Informed Consent Form (ICF) (In English and other local language(s) where applicable) labelled and referred to in the proposal.

(*f*) 3 copies of data collection tools (In English and other local language(s) where applicable) labelled and referred to in the proposal).

(*g*) 3 copies of support letters from Affiliating Institutions i.e. Universities, Hospitals, Research Institutions or Companies where the study is going to take place.

(*h*) 3 copies of curriculum vitae for the Principal Investigator and Co-Investigators.

(*i*) A copy of a deposit slip for the paid application fee of USD150 or its equivalent in Kwacha.

FORM C

APPLICATION FOR ANNUAL CONTINUING REVIEW AND AMENDMENT TO THE INITIALLY APPROVED STUDY PROTOCOL

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

1.1.1 A. STUDY INFORMATION

Commission Research Ethics Committee Protocol #		Expiration date of current approval period:	
Project Title:			
Principal Investigator :			
Institution:			
Phone:		E-mail:	
Contact Person: (If applicable)			
Role on Project:			
Phone:		E-mail:	

1.1.2 B. PROJECT FUNDING

Funding:	☐ Unfunded ☐ Funded Agency/Company Name:
Payment of compliance and capacity bulding fee of 10% of 10% of the budget	☐ Pending Paid ☐ Planned ☐

2 C. PERFORMANCE SITE(S)

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

2.1.1 D. STATUS OF STUDY (*check one*)

2.1.1 Active study

☐ Recruitment/enrolment continues

☐ Accrual complete, research intervention continues

☐ Long-term follow-up

☐ Data analysis only, data collection complete

2.1.2 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.

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*

2.1.3 G. AMENDMENT / REVISION REQUEST *Complete ONLY if Amendment or Revision is requested.*

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

Proposed Amendment(s): List the proposed Amendments and briefly describe the nature of the proposed 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 the Commission's policy concerning research involving human participants in biomedical sciences and I agree:

1. to accept responsibility for the scientific and ethical conduct of this research study;
2. to obtain prior ethics approval from the Commission Research Ethics Committee before amending or altering the research protocol or implementing changes in the approved consent form;
3. to immediately report to the Commission Research Ethics Committee in the biomedical sciences 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; and
5. to complete the Continuing Review and Final Report Forms.

Signature of Principal Investigator ..... Date .....

Write/Typed Name of Principal Investigator

2.1.4 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 Principal Investigator

☐ Progress Report, attached to application

☐ Current copy of Consent Form(s)

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 Commission Research Ethics Committee (if submitting an amendment or modification to original protocol)

☐ Recruitment Information (Adverts Web postings, letters etc., if modified from originally approved recruitment materials)

☐ Additional information PI considers important for review by the Commission research ethics committee

This section is for NHSRC Use only

Comments : _____

_____

_____

Decision : _____

_____

Chairperson's Signature : _____

Date :_____

FORM D (reg. 3(2), (4(2))

APPLICATION FOR APPROVAL OF RESEARCH IN THE SOCIAL SCIENCES AND HUMANITIES

TITLE OF PROPOSAL:

PRINCIPAL INVESTIGATOR:

I declare that the following items are included in this submission;

1. Covering letter of introduction from the investigator . . [ ]
2. A soft copy of the proposal with all the required information as specified below; . . . . . [ ]
   - Proposal Title (on cover page) . . . . . [ ]
   - Names of Investigators and their Qualifications . . . . [ ]
   - Institution of affiliation(local or international) . . . . [ ]
   - Letter from local affiliating institution (international) . . [ ]
   - Introduction/Literature review . . . . . [ ]
   - Problem statement/Justification . . . . . [ ]
   - Main and Specific Objectives . . . . . [ ]

   Description of Methodology/Materials and Methods
   - Study design . . . . . [ ]
   - Study sites/locations . . . . . [ ]

- Study participants . . . . . [ ]
- Study period . . . . . [ ]
- Sampling methods . . . . . [ ]
- Sample size . . . . . [ ]
- Data collection instruments . . . . . [ ]
- Data management methods . . . . . [ ]
- Data analysis method . . . . . [ ]

Research dissemination strategy Ethics

- Risks and strategies for obviating them to enhance protection of rights and welfare of study participants [ ]
- Informed consent form/sheet/assent in English and/or translated into an appropriate local language containing standard elements of an informed consent form/sheet/assent [ ]

Work plan (including roles of collaborators clearly defined) [ ]

Budget (that include a 10% research compliance and capacity building fee on approval of the study) [ ]

Budget justification . . . . . [ ]

Bibliography . . . . . [ ]

3. Data collection instruments translated into appropriate local language and referred to in the annex . . . . [ ]
4. Letter(s) of permission of entry/support from relevant DHO/Head of Health Facility, if the study is going to be conducted in a health facility . . . . . [ ]
5. Letter of approval from foreign ethics committee (for all studying in foreign universities) . . . . [ ]
6. Application/Processing fee of USD 150 or its MKW equivalent [ ]
7. *Curriculum vitae* (CVs) for all the investigators (in annex) [ ]

FORM E (reg. 3(2), (4(2)

APPLICATION FOR AMENDMENT TO THE INITIALLY APPROVED RESEARCH PROTOCOL IN THE SOCIAL SCIENCES AND HUMANITIES

COMMISSION RESEARCH ETHICS REF NO: Commission Research Ethics Committee will not process requests for amendment without this number	Date of Request
Principal Investigator's Name: _____ Phone number: _____ E-mail address: _____	Contact Person (if other than PI) Phone No: _____ E-mail address _____
Title of Study:	

1. Description of proposed changes:
   (Specify the sections, paragraphs and pages at which the proposed changes appear. Such changes must be highlighted)

2. Reason for amendment /modification:

3. Changes to consent form: Are changes required? No_____ Yes_____ (If yes, attach new consent form)

4. Signature of Principal Investigator: Date:

FORM F (reg. 3(2), (4(2))

APPLICATION FOR ANNUAL CONTINUATION APPROVAL OF RESEARCH IN THE SOCIAL SCIENCES AND HUMANITIES

A. STUDY INFORMATION

Commission Research Ethics Committee(REC) Protocol No.		Expiration date of current approval period:	
Protocol Title:			
Principal Investigator:			
Institution:			
Phone No.:		E-mail:	
Contact Person, if other than PI: (If applicable)			
Role of contact person (if applicable) on Protocol:			
Phone No.:		E-mail:	

B. PROTOCOL FUNDING

Funding:		
	☐ Funded	
	Agency/Company Name:	
Payment of 10% fee:	☐ Paid	☐ Unpaid

C. PERFORMANCE SITE(S)

List all performance sites for this study in Malawi

D. STATUS OF STUDY (*check one*)

Active study

☐ Participants recruitment/enrolment continues
☐ Recruitment complete/research intervention continues
☐ Long-term follow-up
☐ Data analysis only
☐ Data collection complete

E. INTERVENTION INFORMATION

Intervention:

☐ If interventional study, describe the intervention:
☐ Survey/Questionnaire
☐ If Other, Briefly explain _____
_____
_____

F. PROGRESS REPORT

1. Enrolment and demographic information: LEAVE NO LINE BLANK

Total number of participants requested in original NCRSH 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 _____ 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.

Adverse events/overall risk: Answer every question.

Based on your knowledge of the adverse events for this study if any, do you feel that there is a significant increase in risks to participants? Has anything occurred since the last NCRSH approval 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/assent (i.e., problems with subject understanding, high refusal rate, etc.)? Explain.

3. Actual Progress Report:

Please attach a brief summary of findings (preliminary or final) obtained in the study, a summary of recent literature or relevant information. 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*.

G. PRINCIPAL INVESTIGATOR'S ASSURANCE STATEMENT

Principal Investigator's Assurance Statement:

I understand the Commission's requirement concerning research involving human participants and I agree to—

(*a*) accept responsibility for the scientific and ethical conduct of this research study;

(*b*) obtain prior approval from Commission and a REC that performed the initial ethics review before amending or altering the research protocol or implementing changes in the approved consent form;

(*c*) immediately report to Commission any serious adverse reactions and/or unanticipated effects on participants which may occur as a result of this study;

(*d*) train study personnel in the proper conduct of human participants research; and

(*e*) to complete the continuing review form.

Signature of Principal Investigator : _____ Date : _____

Write/Type 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/Assent Form/(s)

Include the following only if applicable:

☐ In the case of students, proof of continued affiliation to the study programme must accompany the application package

☐ Adverse Event Summary Table

☐ Additional information PI considers important for review by Commission and a REC

FORM G (reg. 3(2), (4(2))

APPLICATION FOR AUTHORIZATION TO CARRY OUT RESEARCH IN BIOTECHNOLOGY

APPLICATION REFERENCE NUMBER_____
(for official use)

SECTION A
(*To be filled by the Applicant*)

1. Name of the Applicant _____
   Profession _____
   Address _____
   _____
   _____
   Tel: _____ Fax: _____
   E-mail _____ Website _____

2. Name of the institution to which the applicant is affiliated
   _____
   _____
   Address _____
   _____
   _____
   Tel: _____ Fax: _____
   E-mail _____ Website _____

3. Name of the collaborator _____
Qualification and area of expertize _____
   _____
   Address _____
   _____
   _____
   Tel: _____ Fax: _____
   E-mail _____ Website _____

4. Name of the institution to which the collaborator is affiliated

_____

_____

Address _____

_____

_____

Tel: _____ Fax: _____

E-mail _____ Website _____

PART II-INFORMATION RELATING TO THE KIND OF BIOTECHNOLOGY RESEARCH.

5. Detailed explanation on the type of Biotechnology research
   - Basic biotechnology research (microbiology, molecular biology, plant/animal tissue culture).
   - Genetic modification or genome editing research.
   - Contained use of genetically modified organisms (GMOs) in laboratories or greenhouses.
   - Field trials of biotech products (e.g., GM crops).
   - Medical biotechnology (e.g., vaccine development, molecular diagnostics).

_____

_____

_____

_____

_____

_____

INFORMATION RELATING TO APPLICATION REQUIREMENTS

6. Research proposal (objectives, methods, and potential risks).

_____

_____

_____

_____

_____

_____

7. Biosafety and biosecurity measures (compliance with Cartagena Protocol if applicable).

8. Details of laboratory facilities (containment level, safety equipment, waste management).

9. Institutional Biosafety Committee (IBC) approval (if applicable).

INFORMATION RELATING TO APPROVAL CONDITIONS

10. Detailed explanation of the compliance measures with national laws and international treaties

11. Detailed schedule for regulatory inspections by the regulator

12. Explanation of how record-keeping will be managed and how reporting of material usage will be done

_____

_____

_____

_____

_____

13. Detailed information on import, transfer and disposal of biological materials.

_____

_____

_____

_____

_____

SECTION B

(*To be filled by the Certifying Institution*)

14. Has any similar work been done in Malawi? If so explain.

_____

_____

_____

_____

_____

15. Recommendations of the Certifying Institution.

_____

_____

16. Name of the Certifying Institution.

_____

17. Name of the Certifying Officer _____

18. Title of the Certifying officer _____

Address _____

_____

_____

Tel: _____ Fax: _____

E-mail _____ Website _____

Signature of the Certifying Officer _____

(*Official stamp*)

SECTION C.

[*To be filled by Director General of National Commission for Science and Technology*]

19. Application of_____to carry out research in Biotechnology.

(*a*) Decision (Approved /Rejected) _____

(*b*) Reasons (If rejected) _____

_____

_____

Application reference _____

(*c*) Name of the Approving Officer _____

(*d*) Title of the Approving Officer _____

Address _____

_____

_____

Tel: _____ Fax: _____

E-mail _____ Website _____

Signature of the Approving Officer _____

(*Official stamp*)

FORM H (reg. 3(2), (4(2))

APPLICATION FOR AUTHORIZATION TO CARRY OUT RESEARCH INVOLVING GENOME EDITING IN PLANTS AND ANIMALS

APPLICATION REFERENCE NUMBER _____
(*for official use*)

SECTION A
(*To be filled by the Applicant*)

Note: This application form is not for the purpose of exportation of genetic resources

1. Name of the Applicant _____
   Profession _____
   Address _____
   _____
   _____
   Tel: _____ Fax: _____
   E-mail _____ Website _____

2. Name of the institution to which the applicant is affiliated
   _____
   _____
   Address _____
   _____
   _____
   Tel: _____ Fax: _____
   E-mail _____ Website _____

3. Name of the collaborator _____

Qualification and area of expertize _____

_____

Address _____

_____

_____

Tel: _____ Fax: _____

E-mail _____ Website _____

4. Name of the institution to which the collaborator is affiliated

_____

_____

Address _____

_____

_____

Tel: _____ Fax: _____

E-mail _____ Website _____

PART II - INFORMATION RELATING TO THE PARENTAL OR RECIPIENT PLANT

5. The full name of the plant _____

(*a*) family name _____

(*b*) genus _____

(*c*) species _____

(*d*) subspecies_____

(*e*) cultivator/breeding line_____

(*f*) common name _____

6. Information concerning the reproduction of the plant

(*a*) the mode or modes of reproduction

_____

(*b*) any specific factors affecting reproduction

_____

(*c*) generation time

_____

7. Information concerning the survivability of the plant—

(*a*) its ability to form structures for survival or dormancy;

_____

_____

(*b*) any specific factors affecting survivability of the plant.

_____

_____

8. The geographical distribution of the plant.

_____

_____

9. Where the application relates to a plant species which is not normally grown in Malawi, a description of the natural habitat of the plant, including information on natural predators, parasites, competitors and symbionts.

_____

_____

PART III INFORMATION RELATING TO THE GENETIC MODIFICATION

10. A detailed description of the research proposal (objectives, methodology, anticipated outcomes)

_____

_____

_____

_____

_____

_____

11. A description of the methods used for the genetic modification (e.g., using CRISPR-as9, TALENs, ZFNs, etc.).

_____

_____

_____

_____

_____

_____

12. A description of the genes to be edited and what they are responsible for.

_____

_____

_____

_____

_____

_____

13. State the importance and relevance of the proposed study/work to Malawi

_____

_____

_____

_____

14. Clearance from applicants' Institutional Biosafety Committee (IBC), or Ethics Committee, which reviews the safety, ethics, and scientific merit of the proposed research (Should be attached)

15. Signatures _____ Applicant

_____ Collaborator

SECTION B

(*To be filled by the Certifying Institution*)

16. Type of materials to be used in the gene modification (Append copy of request)
    (*a*) Botanical
    (*b*) Zoological
    (*c*) Others (*specify*)
17. Has any similar work been done in Malawi? If so explain.

_____

_____

18. Recommendations of the Certifying Institution.

_____

_____

19. Name of the Certifying Institution.

_____

20. Name of the Certifying Officer _____
21. Title of the Certifying officer _____
Address _____

_____

_____

Tel: _____ Fax: _____

E-mail _____ Website _____

Signature of the Certifying Officer _____

(*Official stamp*)

SECTION C.

[*To be filled by the Chairperson of the National Committee on Agriculture and Natural Sciences.*]

22. Application of_____to carry out research using genome editing

(*a*) Decision (Recommended for approval/rejected) _____

(*b*) Reasons (If rejected) _____

_____

_____

23. Name of the Chairperson _____

Address _____

_____

_____

Tel: _____ Fax: _____

E-mail _____ Website _____

Signature and Date _____

SECTION D.

[*To be filled by Director General of National Commission for Science and Technology*]

24. Application of _____ to carry out research using genome editing

(*a*) Decision (approval/rejected) _____

(*b*) Reasons (If rejected) _____

_____

_____

Application reference _____

(*a*) Name of the Approving Officer _____

(*b*) Title of the Approving Officer _____

Address _____

_____

_____

Tel: _____ Fax: _____

E-mail _____ Website _____

Signature of the Approving Officer _____

(*Official stamp*)

FORM I (reg. 3(2), (4(2))

APPLICATION FOR AUTHORIZATION TO CARRY OUT RESEARCH IN NUCLEAR SCIENCES

APPLICATION REFERENCE NUMBER _____

(*for official use*)

SECTION A

(*To be filled by the Applicant*)

25. Name of the Applicant _____

Profession _____

Address _____

_____

_____

Tel: _____ Fax: _____

E-mail _____ Website _____

26. Name of the institution to which the applicant is affiliated

_____

_____

Address _____

_____

_____

Tel: _____ Fax: _____

E-mail _____ Website _____

27. Name of the collaborator _____

Qualification and area of expertize _____

_____

Address _____

_____

_____

Tel: _____ Fax: _____

E-mail _____ Website _____

28. Name of the institution to which the collaborator is affiliated

_____

_____

Address _____

_____

_____

Tel: _____ Fax: _____

E-mail _____ Website _____

PART II - INFORMATION RELATING TO THE KIND OF NUCLEAR MATERIAL OR RADIATION SOURCES THAT MAY BE USED (*radioisotopes, X-ray generators, particle accelerators, reactors, etc.*)

29. Detailed explanation of the kind of nuclear material or radiation sources that may be used

30. Detailed explanation on whether research is for basic science, medical, agricultural, industrial, or energy applications

INFORMATION RELATING TO APPLICATION REQUIREMENTS

31. Research proposal (objectives, methods, justification for nuclear use)

32. Safety and security measures (radiation protection plans, shielding, monitoring equipment)

33. Facility details (labs, reactors, storage)

34. Waste management plan (handling, disposal of radioactive waste)

INFORMATION RELATING TO APPROVAL CONDITIONS

35. Detailed explanation of the compliance measures with national laws and international treaties (International Atomic Energy Agency safeguards, Non-Proliferation Treaty)

36. Detailed schedule for regulatory inspections by the regulator

37. Explanation of how record-keeping will be managed and how reporting of material usage and radiation exposure will be done

38. Detailed information on Import/Export Licence (for nuclear material or equipment crossing borders)

SECTION B

(*To be filled by the Certifying Institution*)

39. Based on the provisions of the Atomic Energy Act (Cap. 61:03), is the type of nuclear science research allowed in Malawi

(Yes/No)_____

40. Has any similar work been done in Malawi? If so explain.

_____

_____

_____

_____

41. Recommendations of the Certifying Institution.

_____

_____

42. Name of the Certifying Institution.

_____

_____

43. Name of the Certifying Officer _____

44. Title of the Certifying officer _____

Address _____

_____

_____

Tel: _____ Fax: _____

E-mail _____ Website _____

Signature of the Certifying Officer _____

(*Official stamp*)

SECTION C

[*To be filled by the Director General of National Commission for Science and Technology*]

45. Application of_____to carry out research in nuclear science.

(*a*) Decision (approval/rejected) _____

(*b*) Reasons (If rejected) _____

_____

_____

Application reference _____

(*a*) Name of the Approving Officer _____

(*b*) Title of the Approving Officer _____

Address _____

_____

_____

Tel: _____ Fax: _____

E-mail _____ Website _____

Signature of the Approving Officer _____

(*Official stamp*)

FORM J (reg. 3(2), (4(2))

APPLICATION FOR THE ESTABLISHMENT OF AN INSTITUTIONAL RESEARCH ETHICS COMMITTEE FOR CLEARING RESEARCH INVOLVING HUMANS

1.0 Research Ethics Committe Details

Name of a Research Ethics Committee:

Mailing Address of a Research Ethics Commiittee—

(*a*) Physical Address:

(*b*) Postal Address:

(*c*) E-mail Address:

Research Ethics Committee Administrator

(*a*) Name:

(*b*) Address including telephone number(s):

2.0 Organization Hosting a Research Ethics Committee (Applicant with primary responsibility for the Reasearch Ethics Committee)

Name of organization:	
Name of head of organization:	
Position of Head of Organization eg Vice Chancellor:	
Address of Head of Organization (physical, postal and e-mail:	
Telephone numbers of head of organization:	

3.0 Evidence of Approval by the Commission of the Research Ethics Committee's Guidelines and Standard Operating Procedures(SOPs)

Attach a letter of approval issued by the Commission and a copy of the standard operating procedures and guidelines for the research ethics committee, approved by the Commission:

4.0 Research Ethics Committee's membership appointed in accordance with the Commission's approved Guidelines and SOPs

Attach the list of members:

5.0 Signed Statement of Undertaking to remit to the Commission ten per cent of revenue generated by a Research Ethics Committee through research protocol review fees remitted June and December of every year:

6.0 Declaration by Head of Organization

I declare and undertake for the organization that I am duly authorized to sign this declaration and that information supplied on this form and any attachment is true and correct

Name of Organization Head	
Signature and official stamp affixed	
Date	

The covering letter, completed Form together with the attachments forming an application dossier shall be sent to the Director General, National Commission for Science and Technology, Lingadzi House, City Centre, P/Bag B303, Lilongwe 3.

For Office Use ONLY

Date Received:

Application No:

FORM K (reg. 3(2), (4(2))

APPLICATION FOR THE ESTABLISHMENT OF AN INSTITUTIONAL RESEARCH ETHICS COMMITTEE FOR CLEARING RESEARCH INVOLVING ANIMALS

1.0 AREC Details

Name of Animal Research Ethics Committee:

Mailing Address of Animal Research Ethics Committee:

(*a*) Physical Address:

(*b*) Postal Address:

(*c*) E-mail Address:

Animal Resarch Ethics Committee Administrator

(*a*) Name:

(*b*) Address including telephone number(s):

2.0 Organization Hosting Animal Research Ethics Committee (Applicant with primary responsibility for the Animal Research Ethics Committee)

Name of organization:	
Name of head of organization	
Position of Head of Organization e.g Vice Chancellor:	
Address of Head of Organization (physical, postal and e-mail	
Telephone numbers of the head of organization	

3.0 Evidence of Approval by the Commission of the Animal Research Ethics Committee's Guidelines and Standard Operating Procedures(SOPs)

Attach a letter of approval issued by the Commission and a copy of the standard operating procedures and guidelines for the animal research ethics committee, approved by the Commission:

4.0 Animal Research Ethics Committee's membership appointed in accordance with the Commission's approved Guidelines and SOPs

Attach the list of members:

5.0 Declaration by Head of Organization

I declare and undertake for the organization that I am duly authorised to sign this declaration and that information supplied on this form and any attachment is true and correct

Name of Organization Head	
Signature and official stamp affixed	
Date	

The covering letter, completed Form together with the attachments forming an application dossier shall be sent to the Director General, National Commission for Science and Technology, Lingadzi House, City Centre, P/Bag B303, Lilongwe 3

For Office Use ONLY

Date Received:

Application No:

FORM L (reg. 3(2), (4(2))

APPLICATION FOR COLLECTION, STORAGE, TRANSFER AND USE OF HUMAN BIOLOGICAL SAMPLES FOR RESEARCH

Protocol Number as Approved by a Research Ethics Committee:

Title of protocol and its Principal Investigator(PI):

Intention and Justification of collection, transfer, use and storage:

Duration of storage:

Responsible Party:

Location of stored samples:

Transportation of samples:

Ownership of samples:

After all laboratory testing has been completed, describe what will happen to the samples?

To whom will the samples be accessible?

Who will be the controlling officers of the samples?

Signed by

Name of the Principal Investigator:

Name of Co – Principal Investigator:

Name of Institution:

Name of Institution:

Signature:

Signature:

Date Signed:

Date Signed:

(Official use only)

Decision by the Commission Official:

Name and Official Stamp

FORM M (reg. 3(2), (4(2))

APPLICATION FOR THE ESTABLISHMENT OF A TECHNOLOGY TRANSFER OFFICE

Application Reference No.: _____

Confidential: All information submitted will be treated in strict confidence.

Instructions to Applicants

1. Please complete all sections of this form in full.
2. Type or print in block letters.
3. Attach all required supporting documents.
4. Submit both a physical copy and an electronic copy to the Commission.
5. Include the applicable application fee.
6. Processing time is typically thirty working days.

PART A : APPLICANT INFORMATION

(*a*) Full name of Institution:

(*b*) Type of Institution: ☐ University ☐ Research Institute ☐ Private Company ☐ Other:

(*c*) Physical Address:

(*d*) Postal Address:

(*e*) Contacts:Telephone No._____ Mobile _____

E-mail _____ Website (if applicable) _____

(*f*) Name of Contact Person:

(*g*) Designation:

PART B: INSTITUTION BACKGROUND

(*a*) *Introduction (Brief description of your institution, previous activities in technology transfer, gaps identified, and purpose of establishing a technology transfer office (TTO)) maximum 150 words:*

(*b*) *Justification (Alignment with institutional strategy and relevant national/regulatory frameworks)maximum 150 words:*

PART C: TECHNOLOGY TRANSFER OFFICE SET-UP

(*a*) Name of proposed technology transfer office:

(*b*) Location of the technology transfer office:

(*c*) Target users of the technology transfer office:

(i)

(ii)

(iii)

(*d*) Objectives of the technology transfer office:

(i)

(ii)

(iii)

(iv)

(*e*) Fields of science or arts covered by the technology transfer office:

PART D: TECHNOLOGY TRANSFER OFFICE PERSONNEL

Please provide names of officers serving in the posts below and attach their *Curriculum Vitae* and job descriptions:

(*a*) head of technology transfer office;

(*b*) technology transfer officer responsible for commercialization;

(*c*) technology transfer officer responsible for operations;

(*d*) intellectual project specialist;

(*e*) knowledge management specialist;

(*f*) finance officer; and

(*g*) any other employees

Please indicate whether the officers are employed on a full-time or part-time basis.

PART E: COMMITTEES AND GOVERNANCE

Provide names, *Curriculum Vitae* and institutional affiliation for persons in the following committees of the technology transfer office:

(*a*) Advisory board;

(*b*) Technology clearing and/or commercialization; and

(*c*) Others.

PART F: INSTITUTIONAL CAPACITY AND INFRASTRUCTURE

Check the box that applies:

(*a*) Physical office(s) housing TTO: Yes ☐ No ☐

(*b*) Digital storage system for IP and innovation data: Yes ☐ No ☐

(*c*) ICT system for TTO workflow management: Yes ☐ No ☐

PART G: FUNDING AND SUSTAINABILITY

Planned Funding Sources (Tick as applicable):

☐ Institutional budget
☐ Royalties from licensed IP
☐ Equity in spin-offs/start-ups
☐ Licensing fees
☐ Technology Assessment or Clearing services
☐ Consultancy services
☐ Grants and research contracts
☐ Training and capacity building fees
☐ Donations and endowments
☐ Self IP Commercialization
☐ Loans
☐ Other (*specify*): _____

PART H – TRACK RECORD AND PERFORMANCE

Indicator	*Status*	*Brief description*
No. of IP awareness activities		
No. of invention disclosures		
No. of patents granted		
Revenue from licensing		
No. of IP licensed		
No. of spin-offs established		
No. of technology under development		
No. of technology Released		

Attach a description for each indicator

PART I – KNOWLEDGE MANAGEMENT ATTACHMENTS CHECKLIST

(*Tick as applicable and attach the relevant document*)

(*a*) IP Management

☐ Invention Disclosure Form

☐ IP Asset Database

☐ Non Disclosure Agreement Template

☐ Patent Landscape Report Template

☐ Deed of IP assignment Template

☐ IP due diligence report Template

(*b*) Technical

☐ Technology Readiness Assessment Report Template

☐ R&D Agreement Template

☐ Material Transfer Agreement Template

☐ Preliminary Technology Evaluation Template

(*c*) Commercialisation

☐ IP Commercialization Strategy Template

☐ Licence Agreement Template

☐ Licence Terms Sheet

☐ Market Assessment Template

(*d*) Financial Information

☐ Income & Expenditure Template

☐ Benefit Sharing Agreement Template

PART J – SUPPORT INFORMATION

J1: NEW LICENCE APPLICATION INFORMATION

In support of this application for a technology transfer office licence, please submit the following documents:

(*a*) document establishing the institution (registration certificate, Act of Parliament);

(*b*) proof of the Commission's approval of the Technology Transfer Office Guidelines and Standard Operating Procedures (attach the approval letter from the Commission and a copy of the approved Guidelines and Standard Operating Procedures);

(*c*) proof that technology transfer office employees have completed formal training or induction in technology transfer and commercialization provided by the Commission;

(*d*) financial projections for the first year, approved and signed by the Head of the Institution (attach approved budget);

(*e*) institutional intellectual property policy, approved by the Directors of the institution; and

(*f*) evidence of payment of prescribed fees (attach deposit slip).

J2: LICENCE RENEWAL INFORMATION

1. Current License Number: _____
2. Date of Original Licence Issuance: _____
3. Date of Expiry: _____
4. Indicate if there have been any significant changes since the last approval

   ☐Yes ☐No

   If yes, provide a brief explanation: _____

5. Revenue Generation Status: Indicate whether the TTO is currently earning income from:

   (*a*) IP commercialisation (licensing, spinoff) ☐ Yes ☐ No

   (*b*) Technology Readiness assessment services ☐ Yes ☐ No

   (*c*) Consultancy and training service ☐ Yes ☐ No

   (*d*) Other services (*specify*): _____offered by TTO ☐ Yes ☐ No

   For any activity marked 'Yes,' attach supporting evidence of the five percent remittance to the Science and Technology Fund.

6. Attach supporting documentation, including—

   (*a*) a copy of current licence;

   (*b*) evidence of compliance with technology transfer office financial and technical reporting requirements;

   (*c*) updated financial projections;

   (*d*) updated list of employees and their *curriculum vitae*;

   (*e*) evidence indicating new employee and committee members have undergone training by the Commission;

   (*f*) updated list of members of technology transfer office committees and their *curriculum vitae*;

   (*g*) updated institutional intellectual property policy; and

   (*h*) a letter of approval issued by the Commission and a Copy of the Standard Operating Procedures and Guidelines for the technology transfer office.

PART K: DECLARATION

I/We declare that all information provided is true and complete to the best of my/our knowledge and understand that any false declaration may result in refusal or revocation of the licence.

Name of head of the institution: _____

Signature _____

Date _____

PART II (For official use only)

Date Application Received _____

Signature _____

Receipt Number _____

Approved/not approved._____

Date _____

Name: _____

Signature. _____

Director General

National Commission for Science and Technology

(*Official stamp*)

FORM N (reg. 3(3)(*a*))

LICENCE

Licence No…….....

This is to certify that the application to ……
……
……in Malawi received from ..... to the Commission in accordance with the Science and Technology (Licensing of Prescribed Activities) Regulations, 2026, to .....

located.....

has been evaluated and a licence is hereby issued, subject to the attached conditions.

This licence is valid from …….. to .....

Dated this .....day .....20.....

Signature……..... (Official Seal)

Director General

National Commission for Science and Technology

CONDITIONS FOR LICENCES

The conditions for types of licences shall include—

(*a*) Conditions of a licence for Conducting Research Involving Humans in biomedical sciences

(i) Licence validity period is one year.

(ii) Expiration of licence: the research study shall continue only upon renewal, and a progress report shall be submitted one month before expiry.

(iii) Serious adverse events should be reported within twelve to twenty-four hours.

(iv) Submission of a report on the termination of the study.

(v) Submission of the final results of the research study/trial for records.

(vi) Obtain prior ethics approval from the biomedical research ethics committee registered by the commission before implementing any amendments to the research protocol.

(vii) Submit the continuing annual review form if the study goes beyond one year.

(*b*) Conditions of a licence for Conducting Research in the Social Sciences and Humanities

(i) Licence validity period is one year.

(ii) On expiration of a licence, submit the continuing annual review form if the study goes beyond one year.

(iii) Progress report to be submitted when applying for annual continuation has been submitted one month before expiry.

(iv) Serious adverse events should be reported within twelve to twenty-four hours.

(v) Submission of a report on termination of the study.

(vi) Submission of the final results of the research study for records.

(vii) To obtain prior ethics approval from the research ethics committee in the social sciences and humanities registered by the Commission, before implementing any amendments to the research protocol.

(*c*) Conditions of a licence for Conducting Research Involving Genome Editing in Plants and Animals

(i) Licence validity is three years.

(ii) Compliance with any applicable law and regulatory requirements.

(iii) Amendments to the research protocol shall be approved by the designated authority.

(iv) Submission of the technical report at the end of the study.

(v) Continuation approval if the study goes beyond three years.

(*d*) Conditions of a Licence for Access and Collection of Plant Genetic Materials

(i) Adherence to the Prior Informed Consent and Benefit-Sharing Agreement mechanism when exporting genetic resources.

(ii) For foreign researchers, it's mandatory to involve Malawian researchers—explicitly for capacity building purposes.

(iii) To adhere to the Procedures and Guidelines for Access and Collection of Genetic Resources as issued by the Commission and to any other applicable requirements

(*e*) Conditions of a licence for Conducting Research in Nuclear Science

(i) Compliance with national laws and international treaties (International Atomic Energy Agency safeguards, Non-Proliferation Treaty).

(ii) Regular inspections by the regulator.

(iii) Record-keeping and reporting of material usage and radiation exposure.

(*f*) Conditions of a licence for Conducting Research in Biotechnology

(i) Compliance with national biosafety and bioethics regulations.

(ii) Regular reporting and inspections.

(iii) Restrictions on import, transfer and disposal of biological materials.

(iv) Requirement for community/public consultation before field releases.

(*g*) Conditions of a licence for Collection, Transfer, Storage and Use of Human Biological Samples

(i) Validity for a licence is five years.

(ii) Samples shall be collected, transferred, stored and used only for a prospective or retrospective research study approved by a research ethics committee registered with the Biomedical Commission.

(iii) Prior to the collection of samples approval of the biomedical research ethics committee registered by the Commission.

(iv) Any amendment to the MTA Form shall require prior approval by a Commission-registered research ethics committee.

(v) Samples shall not be sold.

(vi) Samples to be used solely for the research purpose.

(vii) Adhere to the applicable access and benefit sharing agreements in Malawi.

(*h*) Conditions of a licence for Establishing a Research Ethics Committee (REC) for Ethics Clearance in Research Involving Humans

(i) The validity of the licence is three years from the date of issuance of the licence.

(ii) The REC shall always act in a manner that protects the safety, rights and well-being of the research participants.

(iii) The REC Secretariat and institution hosting a REC to be open to the Commission's regulatory technical audit of a REC.

(iv) The REC secretariat, members and the institution hosting a REC shall adhere to the Guidelines and Standard Operating Procedures as approved by the Commission.

(v) The REC shall adhere to the REC accreditation requirements and standards as issued by the Commission.

(vi) The REC shall adhere to any applicable regulatory requirements, procedures and guidelines as issued by the Commission in the conduct of research involving humans.

(vii) Members and Secretariat of a REC shall attend courses in research ethics during the tenure of their membership.

(viii) The REC shall carry out periodical inspections of approved studies.

(ix) The REC shall report to the Commission any matters requiring regulatory interventions that are not within the scope of a REC.

(x) The REC shall remit to the Commission ten per cent of revenue generated by it through review of research protocols every six months.

(xi) The REC Secretariat shall submit to the Commission a database of approved research studies every three months in a given fiscal year.

(xii) Any amendments to the REC Guidelines and Standard Operating Procedures shall be submitted for approval by the Commission.

(xiii) Chairperson and Vice Chairperson of a REC to be elected by appointed members from among themselves.

(xiv) REC report covering elements of information indicating how a REC has performed on conditions (ii) to (xiii) to be submitted on application for renewal of a licence.

(xv) Renewal of licence based on REC's performance in adhering to conditions (i) to (xiv).

(i) Conditions of a licence for Establishing a Research Ethics Committee for Ethics Clearance in Animals

(i) Licence validity is three years from the date of issuance.

(ii) The REC shall always promote the welfare of animals in research.

(iii) The REC shall remit to the Commission ten per cent of revenue generated by it through review of research protocols every six months.

(iv) Any amendments to the Animal Research Ethics Committee Guidelines and SOPs to be submitted for approval by the Commission.

(*j*) Conditions of a licence for Establishing a Technology Transfer Office

(i) Licence validity is five years from the date of issuance.

(ii) The licence shall only be used for the establishment and operation of a Technology Transfer Office (TTO) as specified in the approved application, and shall remain valid for the designated period and location.

(iii) Neither the licence nor any right thereunder shall be transferred, assigned, or disposed of in any manner, either voluntarily or involuntarily, directly or indirectly, through transfer of control of the licence to any person.

(iv) The Commission reserves the right to cancel the licence at any time if the TTO fails to operate in accordance with the provisions of the Science and Technology Act, relevant national laws, or the conditions outlined herein. Non-compliance with institutional intellectual property policies, financial and technical reporting, or operational guidelines may also result in revocation.

(v) The Commission shall conduct periodic inspections of the TTO's activities, records, and facilities to verify compliance with this licence and applicable regulations.

(vi) Inspections may be scheduled or unannounced and shall cover—

AA. Financial records and revenue remittance;

BB. IP management and commercialisation activities;

CC. Staff qualifications and training documentation; and

DD. Adherence to approved SOPs and institutional policies.

(vii) The licensee shall provide full cooperation during inspections, including access to all requested documents and personnel.

(viii) The licensee shall, upon request by the Commission, submit written statements and reports (including financial reports, performance metrics, and compliance documentation) under oath or affirmation to facilitate the Commission's assessment of whether the licence should be modified, suspended, or revoked.

(ix) The licensee shall remit five per cent of gross income generated from—

AA. intellectual property commercialization (including licensing fees, royalties, and spin-off revenue(equity sales, dividends, any other financial gains from spin-off company); and

BB. other commercial services offered by the TTO (including consultancy, technology assessment, and training fees) to the Science and Technology Fund every six months.

(x) Proof of payment (deposit slips or bank transfer receipts) shall be submitted to the Commission within thirty days of each remittance.

(xi) Failure to comply may result in penalties, suspension, or cancellation of the licence.

(xii) The licensee shall ensure all TTO staff and committee members undergo mandatory training or induction programs approved by the Commission.

(xiii) Changes in personnel shall be reported promptly, with updated *Curriculum Vitae* and job descriptions submitted to the Commission.

(xiv)The Commission reserves the right to modify the conditions of this licence, including its cancellation, without prior notice, to align with changes in national policies, regulatory frameworks, or public interest.

Dated……..

Director General

National Commission for Science and Technology

FORM O (reg. 7(1))

REGISTER FOR LICENSEES

No.	*Name of licensee*	*Address*	*Phone*	*E-mail*	*National ID/ Company registration number*	*Application reference number*	*Nature/ title of activity*	*Location*	*Type of licence or permit Issued*	*Licence or Permit number*	*Date issued*	*Expiry date*	*Remarks*

SECOND SCHEDULE (reg. 3(2), 3(4), 4(2)(*c*))

FEES

TYPE/DESCRIPTION OF SERVICE	*CURRENCY/ UNIT*	*APPLICATION FEE*	*LICENCE FEE*	*RENEWAL FEE*
Regulatory endorsement of the initial no-fault type insurance for clinical trial participants	K	1,200,000	Free	Free
Regulatory endorsement of any renewed no-fault type insurance for clinical trial participants	K	600,000	Free	Free
Access and Collection of Plant and Animal Genetic Resources—	USD		Free	Free
(*a*) Research and Training Institutions		450		
(*b*) Non-profit organizations		900		
(*c*) Commercial Entity		2,500		
An application/processing of ethics review of research study protocol payable on submission of the application package	USD	150	-	Free
Review and approval of research studies in the social sciences and humanities, and in the biomedical sciences involving humans that were under review by a research ethics committee.	% of USD or K	10 % of the specific research study budget as contained in a specific research protocol under review being compliance and capacity building fee for human subject protection) payable prior to making an issuance of the ethics approval of a research protocol	Free	Free

TYPE/DESCRIPTION OF SERVICE	*CURRENCY/ UNIT*	*APPLICATION FEE*	*LICENCE FEE*	*RENEWAL FEE*
Review and approval of research studies involving animals that were under review by an animal research ethics committee	% of USD or K	10 % of the specific research study budget as contained in a specific research protocol under review by an animal research ethics committee, being compliance and capacity building fee for animal subjects welfare payable prior to making an issuance of the ethics approval of a research protocol	Free	Free
Authorization to carry out research in Malawi using Genome editing in plants and animals	USD	1200	Free	Free
Authorization to carry out Nuclear Science research in Malawi.	USD	1200	Free	Free
Authorization to carry out Biotechnology research in Malawi.	USD	1200	Free	Free
Application for Establishment of a Research Ethics Committee for Ethics Review and Clearance of Research Studies in Humans and Animals	US$	150	100	Free
Establishment of an institutional Technology Transfer Office	US$	875	30	300

Made this 23rd day of April, 2026.

B. MSAKA, SC

Minister of Education, Science and Technology

(REF.: NO. NCST/RTT/1/20)

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