MEDICAL RESEARCH COUNCIL OF ZIMBABWE APPLICATION TO CONDUCT RESEARCH

Instructions and Guidelines on Submitting an Application for Registration to Conduct Research

INSTRUCTION: Please tick in the applicant column as appropriate

	ITEM	Applicant	MRCZ
1.	**A completed application form.**		
2.	**CATEGORY: REGISTRATION FEES PAID**		
	A US **$500** for **Individual Researcher / studies** *(Turnaround time: 4 - 6 weeks)*		
	AE US **$1 000** for **Fast Track Review (New Studies)** *(Turnaround time: 2 weeks)*		
	E US **$200** for **Exempted from Ethics Review (New Studies)** *(Turnaround time: 2 weeks)*		
	BP US **$200** for **PhD** *(Turnaround time: 4 - 6 weeks)* US **$50** for **MSc** *(Turnaround time: 1 week)*		
	BU US **$10** for **Undergraduates** *(Turnaround time:2 days)*		
3.	**Masters & BSc to submit 2 CLEARLY LABELED flat files copies** of the following documents:		
	a. Research **proposal summary** *(maximum 4 pages)*		
	b. Full **research proposal**		
	c. **Informed consent forms**: *English & Vernacular Versions. (Shona/ Ndebele/ appropriate language)*		
	d. Letter of support from supervisor		
	e. University Research Ethics Committee /IRB approval		
	e. Supplementary information as applicable.		
	f. **Permission letter from head of institution** where data is to be collected (*For research in schools, a letter from ministry of Education is a requirement).*		
4.	**BP (PhD) studies to submit 4 CLEARLY LABELED flat files (1 original plus 3 copies) of the following documents :**		
	a. Letter from academic supervisor confirming that s/he has authorized submission of proposal to MRCZ		
	b. Name, contact details and detailed curriculum vitae of academic supervisor(s)		
	c. For candidates registered with foreign institutions, please provide name contact details and letter from proposed local co-supervisor/adviser confirming willingness to supervise/advise		
	d. Four Copies of the following documents (1 original plus 3 copies):-		
	1. Completed MRCZ application form		
	2. Research proposal summary *(maximum 4 pages)*		
	3. Informed consent forms *(English and applicable local languages)*		
	4. Specimen Storage and shipment consent form. *(English and applicable local languages)*		
	5. Questionnaires & Any other data collection tools *(English and applicable local languages)*		
	6. Full research proposal (*hard copy and electronic version)*		
	7. Drug brochure or supplementary information if applicable		
	8. CVs for the P.I and Co-Investigators		
	e. University Research Ethics Committee /IRB approval		
	f. Permission letter from head of institution where data is to be collected (*For research in schools, a letter from ministry of Education is a requirement).*		
5.	**A , AE & E studies to submit 4 CLEARLY LABELED flat files (1 original plus 3 copies) of the following documents :**		
	a. Research **proposal summary** *(maximum 4 pages)*	x	
	b. Full **research proposal** and an **electronic version** as well.		
	c. **Informed consent forms** *: English & Vernacular Versions (Appropriate vernacular language)*	x	
	d. **CVs** for the P.I and Co-Investigators	x	
	e. **Drug brochure or supplementary information** if applicable.		
	f. Permission letter from head of institution where data is to be collected (*For research in schools, a letter from ministry of Education is a requirement).*		
	g. Proof of funding on Sponsor's Letterhead	x	

Registration fees should be paid into the MRCZ Account :

Account Name : Medical Research Council of Zimbabwe
Bank Name : CBZ
Branch : Kwame Nkrumah
Swift Code : COBZZWHA
Branch Sort Code : 6101
Account Number : 01120068040016

For Office Use Only	**Date received...../...../.....**
MRCZ/...../.....	**FC ☐ EXP ☐ XMPT ☐**

A. DETAILS OF RESEARCH TEAM

1. Name of Principal Investigator (P.I)	MR. S. GAVURE			
2. Nationality of P.I	Zimbabwean			
3. Existing Qualifications	BED in ENVIRONMENTAL SCIENCE			
4. Academic Title	BIOLOGY TEACHER			
5. Institution & Dept.	KRISTE MAMBO HIGH SCHOOL			
6. Postal address	PRIVATE BAG 8095 RUSAPE			
7. E-mail address	admin@kristemambo.co.zw			
8. Telephone No.	0775 253 117\ 0712 768 828			
9. Is this research expected to lead to the award of a higher degree for the PI or any other research team member? (Yes/No)	No			
10. Degree Type	**Undergraduate (BSc, BA,etc)**	**MSc/MA/MMed/ MPhil**	**PhD/DPhil**	**Other**
11. Name of students if not the PI	N/A			
12. University/Institution where student is registered	KRISTE MAMBO HIGH SCHOOL			

13. Students # and Year of Study

Name	Surname	Class	Sex
IRENE	TAKUNDWA	Upper 6	F
HAZEL	MUJATI	Upper 6	F
MAZVITA	WUTA	Upper 6	F
NYASHA	CHIHAMBIRO	Upper 6	F
MERCY	MUTEMA	Upper 6	F
MITCHELL	CHAUKURA	Upper 6	F
TINEVIMBO	CHIFEMA	Form 4	F
ENGELENE	BAYAI	Form 4	F
CHRISTABEL	NYAMBODZA	Form 4	F
NYASHA	JIM	Form 4	F

Co-investigators Names	Qualifications	Institution/Department
14. Ms. T. Machaka	Teacher	Kriste Mambo High School
15. Dr Rosyln Thelingwani	Chemist (PhD)	African Institute of Biomedical Science and Technology, Zimbabwe
16. Prof. Collen Masimirembwa	PhD	African Institute of Biomedical Science and Technology, Zimbabwe
17. Dr. Karembo	Doctor/~~Dematologist~~	Rusape General Hospital

(Add rows if required)

Advisory Committee

Name	Role	Contact
Mr. S. Gavure	Male Teacher	0775 253 117
Ms. T. Machaka	Female Teacher	0777 073 107
Fr. A. Makokowe O.Carm	Religious Leader	0772 391 112
Mr. T. Shayi	Male Parent	0774 222 474
Mrs Chifema	Female Parent	0719 225 412
MP (Headlands Constituency) Mr. C. Chingosho	Member of Parliament (ward 10)	0776 235 224\ 0718 218 357
Headman T.Chiro	Sabhuku	O773 362 550
Mr. T. Jinjika	Councilor(ward 10)	0773 286 379
Mr J.P Mangundya	Businessman	02242703000

B. DETAILS OF RESEARCH COORDINATOR

1.	Name	Mr. S. Gavure
2.	Postal Address	Kriste Mambo High School
3.	E-mail Address	simomogav@gmail.com
4.	Telephone Number	-
5.	Mobile Number	0775 253 117\ 0712 768 828
6.	Site where Coordinator is stationed	Kriste Mambo

C. DETAILS OF THE PROPOSED RESEARCH

1.	Title of proposed research	**Effects of school water on the skin of students at Kriste Mambo**
2.	Proposed starting date	**1 April 2019**
3.	Proposed ending date	**31 March 2020**
4.	Performance site(s) in Zimbabwe	**Zimbabwe**
5.	Performance sites (outside Zimbabwe)	**N/A**

6. Total number of study personnel	22
7. Budget (state currency & amount)	**5 000 RTGSS**
8. Name and address of Funding agency:	**African Institute of Biomedical Science and Technology**
9. Status of funding :	a)Submitted for funding ☐ b)Pending ☐ c) Funded ☐x

D. COLLABORATING INSTITUTIONS

	Institution	Contact / Focal Person (Name)	Telephone #	Email
1.	African Institute of Biomedical Sciences & Technology (AiBST)	Frank Muzenda	0783300868	fmuzee@gmail.com
2.	Rusape General Hospital	Dr Karembo	0773 707 147	rusapehospitalmedsup@gmail.com
3.	Rusape water Quality Services	Mr .B. Gwamura	0776 078 373	bgwamura@gmail.com
4.				

(Add rows if required)

E. POPULATION

Population: Proposed inclusion criteria

(Check all that applies)

Males	: ☐X
Females	: ☐X
Adolescents (12 – 17 years)	: ☐ X
Children (Under 12 years of age)	: ☐
Pregnant women	: ☐
Foetuses	: ☐
Elderly (over 65 years)	: ☐
Prisoners	: ☐
Cognitively impaired	: ☐
Hospital inpatients	: ☐
Sexual Minorities	: ☐
Sex Workers	: ☐

F. TYPE OF STUDY

Type of study *(check all that applies)*

Survey	: ☐ X
Secondary data	: ☐
Observational Clinical Trials	: ☐
Clinical trial	: ☐
Lab Based/Biomedical Research	: ☐ X
Record review	: ☐
Operations Research	: ☐
Qualitative/Social/Behavioural	: ☐ X
Device Study	: ☐

Other (specify) : .....

G. DETERMINATION OF RISK *(Check all that applies)*

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

NOTE: Study involves collecting cattle blood.

H. FOR OFFICIAL USE ONLY

Risk of proposed research

A) Minimal risk X

B) Greater than minimal risk ☐

C) High 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.

I. TRAINING

Has the research team undergone training in the following as appropriate:	YES	NO	If No please give dates when this will be done
1. Research Ethics /Human Subjects Protection	☐	☐	
2. ICH-GCP	☐	☐	
3. Good Clinical Laboratory Practices	☐	☐	
4. Good Data Management Practices	☐	☐	
5. Other (Specify if the team has taken any other similar/equivalent training)	☐	☐	

J. CONFLICT OF INTEREST

DECLARATION OF PRINCIPAL INVESTIGATOR

I [Name of teacher] Mr. S. Gavure declare that all potential conflicts of interest regarding my application for ethics approval to conduct this study have been declared in the protocol/proposal.

Conflict of Interest includes but not limited to reporting :

- Having a financial and/or business interests in the source of funding
- Being a consultant for the source of funding
- Receiving funding from a sponsor that may be affected by the research reported in the study

Yes		**No**	**X**

If Yes, please give details in a separate document that show that there is a plan in place for managing any potential conflicts of interest arising

I understand and accept that all information pertaining to this application is a true reflection of the project proposed and I take full responsibility should there be any transgression.

SIGNATURE OF PRINCIPAL INVESTIGATOR.....Gavure.....**DATE**.....22/03/19.....

K. STATISTICAL PLANNING AND DATA ANALYSIS

1. Has this project been reviewed by a professional statistician? N/A If No, please justify below. Exploratory study on population genetics	Yes		No	
2. If answered "yes" to (1), provide details of the statistician				
3. Proposed sample size:				

L. CONSENT PROCESS

1. Consent Process *(Check all that applies)*

Written: ☐x

Verbal/Oral: ☐

2. Consent Language *(Check all that applies)*

English: ☐ x

Local Languages *(List them below)*

Shona

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.....

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L. CLINICAL TRIALS						
1. Has Medicines Control Authority of Zimbabwe (MCAZ) approval been applied for?	Yes		No		N/A	x
2. Is the PI presently involved in other research and/or clinical trial activities? (*If yes, please provide details and % time allocated to each below)* *Carina Schlebusch is involved in several other research projects and the current Zimbabwe project will be allocated 10% of her research time.* *Ezekia Mtetwa is the project manager for Zimbabwe and will allocate 100% of his full time towards the Zimbabwe project.* *Cecile Jolly is the Lab Manager for the Schlebusch Lab and will be in charge of sampling of sputum in Zimbabwe, shipment to Sweden and laboratory work at Uppsala University.* *Various additional members of the Schlebusch lab will also work on the project at different stages (i.e. analyses and manuscript writing in Sweden).*	Yes		No			

3. Which of the following will be used? **N/A**
   - ☐ a) investigational drug(s)
   - ☐ b) new therapeutic applications of MCAZ approved drug (s)
   - ☐ c) new combination of any of the above
   - ☐ d) medical device

4. Briefly describe how this drug or device is a part of the proposed investigation. N/A

5. For each drug or device to be used, please provide the following information: N/A

Generic Name _____ **Trade or Brand Name** _____ **Manufacturer** _____

6. Please give the risks, hazards, known contraindications. N/A

7. Please give reasons for choice of drug(s) for this study. Include pertinent animal clinical tests or appropriate citations. N/A

8. Please provide dose schedule, route of administration, and duration of therapy. N/A

9. Please describe assessment of patient while receiving therapy including clinical observations and laboratory tests. N/A

RESEARCH PROPOSAL SUMMARY

It is the MRCZ requirement that the composition of the Institutional Review Board (IRB) include individuals with varied backgrounds and education. Investigators are therefore required to attach (5) copies of a (maximum 4 pages) Research Proposal Summary using the headings provided below in terminology that is understandable across disciplines.

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 participants, 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.
   - Participants' state of physical health. Indicate if healthy, ill, seriously ill or terminally ill.
   - Does the study involve any special populations: Participants will include: minors, fetuses, pregnant women, prisoners, mentally retarded, mentally disabled, or none of the above.
   - If participants are from one of the above special populations, explain the necessity for including them.
   - Specify source of participating participants, 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 MRCZ for review and approval prior to its publication and/or posting.*
   - List all research procedures and/or interventions involving human participants (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, application for biospecimen shipment and Foreign Researcher registration should be made to Research Council of Zimbabwe through MRCZ, please justify including how the samples are to be shipped, *forms obtainable from RCZ website*).
   - 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 MRCZ.
   - Methods of intervention: Will any new drugs or biologic agents be administered to the participants, 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 Zimbabwe (MCAZ) and may not conduct your study without the approval of both the MCAZ and the MRCZ. 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)

RISKS / BENEFITS TO PARTICIPANTS

- 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 participants and explain why the benefits outweigh the risks.

- Assess benefits which may accrue to society in general as a result of the planned work.

COSTS , COMPENSATION AND REIMBURSEMENTS

- Will participants receive any compensation, monetary or other? If monetary, how much? Will participants 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.

CONFIDENTIALITY ASSURANCES

Describe any means by which the participant'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

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?

COLLABORATIVE AGREEMENTS

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

INTENDED USE OF RESULTS

- Include plans for dissemination and utilization of study results

OTHER INFORMATION:

- Any other information.

FULL RESEARCH PROPOSAL

Attach 5 COPIES of the full research proposal. The full proposal should include the following: Title, objectives, background and literature review, methodology (to include research design, participants and methods, ethical considerations, timetables etc. references, budget etc. 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,
Qualifications,
Ongoing Research Activities and role or % time allocated for each
Past research experience (relevant) and
Published Papers (relevant)
Principal Investigators or co-investigators who would have already submitted their CVs during the current year are exempted from this requirement.

INFORMED CONSENT

- Any kind of contact with human participants requires a disclosure/consent process.
- Attach a copy of the consent form (template is provided on the website www.mrcz.org.zw).
- Indicate how (written) informed consent will be obtained
- If participants 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 MRCZ).

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 Medical Research Council of Zimbabwe's policy concerning research involving human participants (CIOMS Guidelines or Helsinki Declaration) and I agree:

(Please check all that applies)

1. x☐to accept responsibility for the scientific and ethical conduct of this research study;
2. x☐to obtain prior approval from the relevant IRB as well as the MRCZ before amending or altering the research protocol or implementing changes in the approved consent form;
3. x☐to immediately report to the relevant IRB and the MRCZ any serious adverse reactions and/or unanticipated effects on participants which may occur as a result of this study;
4. x☐to complete and submit the Continuing annual Review Form annually (when due) as well as the Final/Study termination form at the end of the proposed study.
5. x☐to submit the final study report to the MRCZ using standard form (MRCZ Termination Form 105).
6. x☐to pay one percent levy to the MRCZ upon approval of my protocol (for study monitoring and general research participants protection requirements).

Signature Gavure [Name of teacher] Date 22/03/19

Print name Mr. S. Gavure

Signature of Co-investigator Machaka Date 22/03/19

[Name of 2nd teacher]

Print Name Ms. T. Machaka

SUBMIT FOUR COPIES OF THE ENTIRE APPLICATION PROPOSAL TO THE MRCZ OFFICES (The entire application package includes the application form, research proposal summary (2-3 pages), full research proposal (even in funding agency format), consent form and other relevant documents).

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INSTITUTIONAL ETHICAL REVIEW BOARD REVIEW AND ENDORSEMENT REQUIRED

Statement from the Institutional Ethics Review Board:

The MRCZ will only accept for review and approval research proposals that have been found both scientifically and ethically acceptable by an Institutional Ethics Review Board (IERB) recognised and operating in accordance with the Guidelines on Institutional Ethical Review Boards set by the MRCZ. In the case of institutions without IERBs, investigators are advised to seek advise from the MRCZ Office.

We the **Institutional Ethics Review Committee** established by

.....

(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 and ethical merit of this study and the competency of the investigator(s) to conduct the project and do hereby recommend the proposal to the MRCZ for approval.

SIGNATURES

Date

Signature
Ethics Committee representative _____ _____

Name (Please Print) _____

Signature : Head of Ethics Committee
(or other authorized signatory) _____ _____

Name (Please Print) _____

Contact Tel. Number :.....

E-mail address : .....

OFFICIAL STAMP OF INSTITUTION

****Institution includes Universities, Hospitals, Research Institutes or Companies.***

Last Updated : 09 February 2016