

Joint Research Ethics Committee for the University of Zimbabwe Faculty of Medicine and Health Science and the Parirenyatwa Group of Hospitals

APPLICATION FORM

Details of Research Team

Details of the Proposed Research

HAS THIS PROPOSAL RECEIVED PRIOR ETHICAL REVIEW BY ANOTHER RESEARCH ETHICS BOARD?

Y / N

Population : Proposed inclusion criteria <i>(Check all that apply)</i> Males : Females :	Name of Principal Investigator (P.I)			
	Qualifications			
	Title			
	Institution & Dept / Unit			
	Title of proposed research.			
	Postal address			
	E-mail address			
	Proposed starting date			
	Telephone No			
	Proposed ending date			
	Mobile Telephone No			
	Performance site			
	Is this research expected to lead to the award of a higher degree (Yes/No)			
	Total number of study personnel			
	University/Institution where registered		Type of study <i>(check all that apply)</i>	
Proposed Sample Size				
Supervisors/ Co-investigator		Qualifications		
Budget (State currency)		Institution/Department		
Name and address of Funding agency:		Clinical Trial :		
Status of funding :		a)Submitted for funding b)Pending c)Funded		
Contact Person (if different from PI)		Secondary data		
Name		Program Project		
Phone Number		Clinical community trial		
Email address				
Adolescents (12 – 17 years) :		Case control		
Children (Under 12 years of age) :		:		
Pregnant women :		Longitudinal study :		
Foetuses :		Record review :		
Elderly (over 65 years) :		Course activity :		
Prisoners :		Other (specify) :		
Cognitively impaired :				
Hospital inpatients :				
Consent Process <i>(Check all that applies)</i> Written : Oral : Languages : None : N/A				
Reading level of consent document: Primary, Secondary, Tertiary				

Does the research involve any of the following	YES	NO
Human exposure to ionizing radiation		

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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 behaviour		
Is the information going to be recorded in such a way that participants can be identified		
Does the research deal with sensitive aspects of the participants 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 participant's financial standing, reputation and employability?		

Determination of Risk *(Check all that applies)*

☒ Do you consider the proposed research

- A) greater than minimal risk
- B) minimal 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.

EXECUTIVE SUMMARY

Investigators are required to attach a 2-3 page (maximum 4 pages) Research Proposal Summary using the headings provided below in terminology that is understandable across disciplines.

1. **TITLE**
2. **RESEARCH QUESTION TO BE ADDRESSED BY THIS PROPOSAL**
3. **RATIONALE FOR RESEARCH**

Describe briefly the background of the study, and state reasons for conducting it.

State objectives of study.

4. **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, and 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.

Participant's state of physical health. Indicate if healthy, ill, seriously ill or terminally ill.

Special populations, such as, minors, fetuses, abortuses, pregnant women, prisoners, mentally retarded, mentally disabled.

If participants are from one of the above special populations explain the necessity for including them.

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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 IRB, 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 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 IRB.

Methods of intervention.

Will any new drugs or biologic agents be administered to the subjects, or will previously used agents be used in a new manner?

If **yes**, please note that you are also required to file a separate application with the Medicines Control Authority of Zimbabwe (MCAZ) and may not conduct your study without the approval of the MCAZ.

Methods for dealing with adverse events

Methods for dealing with illegal, reportable activities (e.g. child abuse)

5. 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.

6. COSTS AND COMPENSATION

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, and cost of study drug if it becomes commercially available, etc.

7. INFORMED CONSENT

Any kind of contact with human participants requires a disclosure/consent process.

Attach a copy of the consent form. Indicate how (verbal or 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).

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8. 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

9. 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?

10. COLLABORATIVE AGREEMENTS

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

11. INTENDED USE OF RESULTS

Include plans for dissemination and utilization of study results

DOES THE STUDY INVOLVE THE TESTING OF DRUGS AND DEVICES? Y/N

DRUG / DEVICE INFORMATION FORM

Please note that you are required to submit a separate application to the Medicines Control Authority of Zimbabwe for authorization to test a drug or medical device.

- 1.** Which of the following will be used?
 - a) Investigational drug(s)
 - b) New therapeutic applications for MCAZ approved drug (s)
 - c) New combination of any of the above

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d) Medical device

2. Briefly describe how this drug or device is a part of the proposed investigation.

3. for each drug or device 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 give reasons for choice of drug(s) for this study. Include pertinent animal clinical tests or appropriate citations.

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

7. Please describe assessment of patient while receiving therapy including clinical observations and laboratory tests.

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SIGNATURE ASSURANCE SHEET

Principal Investigator's Assurance Statement:

I certify that the information given by me is correct to the best of my knowledge and I agree:

(Please check all that applies)

1. to accept responsibility for the scientific and ethical conduct of this research study;
2. to obtain prior approval from the IRB before amending or altering the research protocol or implementing changes in the approved consent form;
3. to immediately report to the IRB any serious adverse reactions and/or unanticipated effects on participants which may occur as a result of this study;
4. 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.

Signature: _____

Date: _____

Print Name: _____

Signature of Supervisor: _____
/ Co-investigator

Date: _____

Print Name: _____