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

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

Supervisors/ Co-investigator	**Qualifications**	**Institution/Department**
Contact Person	Name	Phone Numer & email address

Details of the Proposed Research

Title of proposed research.	
Proposed starting date	
Proposed ending date	
Performance site	
Total number of study personnel	
Proposed Sample Size	
Budget (state currency)	
Name and address of Funding agency:	
Status of funding :	a)Submitted for funding b)Pending c)Funded

Has this proposal received prior ethical review by another Research Ethics Board?

Population : Proposed inclusion criteria *(Check all that apply)*	**Type of study** *(check all that applies)*
Males :	Clinical Trial :
Females :	Survey :
Adolescents (12 – 17 years) :	Secondary data :
Children (Under 12 years of age) :	Program Project :
Pregnant women :	Clinical community trial :
Foetuses :	Case control :
Elderly (over 65 years) :	Longitudinal study :
Prisoners :	Record review :
Cognitively impaired :	Course activity :
Hospital inpatients :	Other (specify) : ……..
Consent Process *(Check all that applies)* 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		
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 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 subjects 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
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.

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.

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.

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

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 IRB, 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 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)

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.

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.

INFORMED CONSENT

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

Attach a copy of the consent form. Indicate how (verbal or written) informed consent will be obtained 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 MRCZ).

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

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

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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
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.

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 subjects 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/ Coinvestigator: _____
Date:_____

Print Name: _____