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

Application for Continuing Review of Research Activity

PLEASE COMPLETE ALL THE RELEVANT FIELDS

The JREC follows at minimum the regulations set forth in the CIOMS Guidelines as the criteria for continuing review. The Continuing Review process must be no less stringent than the initial review.
In the continuing review of ongoing research, the entire study will be reviewed to ensure the continued protection of the rights and welfare of the human participants.
The Principal Investigator is responsible for timely submission (**at least 1 (one) month before expiry of approval date**) of a continuing review application to prevent any lapse in the approval. JREC regulations do not provide for exceptions to the requirement for continuing review. Failure by the Principal Investigator to ensure timely review is a serious matter that will incur a penalty or lead to suspension or termination of the study. **NO EXTENSIONS CAN BE GRANTED.**

A. STUDY INFORMATION

JREC Protocol #		Expiry date of current approval period:	
Project Title:			
Principal Investigator :			
Institution:			
Phone:		Email:	
Contact Person: (If applicable)			
Role on Project:			
Phone:		Email:	

B. PROJECT FUNDING

Funding:	☐ Unfunded ☐ Funded Agency/Company Name:

C. PERFORMANCE SITE(S)

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

D. STATUS OF STUDY (check one)

Active study

☐ Recruitment/enrollment continues

☐ Accrual complete, research intervention continues

☐ Long-term follow-up

☐ Data analysis only, data collection complete

E. INTERVENTION INFORMATION

Intervention:

☐ Drug ☐ Device ☐ Genetic study ☐ Tissues

☐ Survey/Questionnaire ☐ Radiation Use ☐ Medical Record Review

☐ Other, Briefly explain _____

Drug/Device name: _____

_____ _____

F. PROGRESS REPORT (since last review)

IT IS MANDATORY TO COMPLETE ALL THE RELEVANT FIELDS IN THIS SECTION

1. Project Summary (Half a page covering Main Aim, objectives, rationale/justification**)**

2. Narrative summary of progress (Half a page**)**

3. Enrollment and demographic information: Leave No Line Blank.

(i) Total number of participants requested in original JREC application

(ii) Number of participants enrolled since last progress report

(iii) Total number of participants enrolled since the start of the study

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

(v) Currently active in study

(vi) Follow-up data collection only

(vii) Completed intervention and any follow-up

(viii) Lost to follow-up

4. Adverse Events, Complications, Study Withdrawals

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

If yes, please attach the Adverse Event log (JREC Template should be used)

Adverse events/overall risk: **Answer every question**

(ii) Based on your knowledge of the adverse events for this study, do you feel that there is a significant increase in risks to participants? ***If yes, explain***

(iii) Has anything occurred since the last JREC & IRB review that may have altered the risk/benefit relationship? ***If yes, explain***

(iv) Did you withdraw any participant(s) from your study because of a problem or complication? ***If yes, explain***.

(v) Did any participant(s) withdraw themselves from your study? ***If yes, explain***

(vi) Did any problems occur in obtaining or documenting informed consent (i.e. problems with participant understanding, high refusal rate, etc?) ***If yes, explain***

Protocol Deviation / Violation Log

In the past approval period, did any protocol deviations / violations occur? ☐Yes ☐ No

If yes, please attach the Protocol Deviation / Violation log

5. Number of Amendments to date

6. (a) Are you still within the initially applied study duration?

☐ Yes ☐ No

(b) If **No**, please apply for extension of study duration.

7. Brief summary of findings to date (preliminary or final)

If there are no findings at this time, this should be stated and explained

8. List of DSMB Reports and the Outcomes thereof *(if applicable)*

9. Positive Outcomes e.g Capacity Building

10. **Challenges**

11. **List of Publications (***since last review***)**

Principal Investigator's Assurance Statement:

I understand the JREC's policy concerning research activities and I agree:

1. to accept responsibility for the scientific and ethical conduct of this research study,
2. to obtain prior approval from JREC before amending or altering the research protocol or implementing changes in the approved consent form,
3. to report to JREC any serious adverse reactions and/or unanticipated effects on participants which may occur as a result of this study (Annual summary)
4. to train study personnel in the proper conduct of human participants research,

Signature of Principal Investigator Date

Type Name of Principal Investigator

G. 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	☐
Include the following only **if applicable**:	
1. Adverse Event Summary log.	☐
	☐
	☐
	☐
	☐
	☐
	☐