## 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

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 <u>entire</u> 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 STUD	Y (check one)				
Active study  Recruitment/enrollment conti	inues				
Accrual complete, research in					
☐ Long-term follow-up☐ Data analysis only, data collection	ction complete				
3					
	NEODI ATION				
E. INTERVENTION I	INFORMATION				
	Device	☐ Genetic study	☐ Tissues		
☐ Survey/Questionnaire ☐	Radiation Use	☐ Medical Record Review			
Other, Briefly explain					
Drug/Device name:					
F. PROGRESS REPO	`				
11. Project Summary (Half					
2. Narrative summary of	f progress (Half a page)				
	- L - a 2 - con ( - min a baile)				
3. Enrollment and demographic information: Leave No Line Blank.					
(i) Total number of participal original JREC application (ii) Number of participants expresses report	on				

(iii	
<i>(</i> :	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)	
(vi	
(vi	i) Completed intervention and any follow-up
(vi	•
	Adverse Events, Complications, Study Withdrawals
٠.	Traverse Events, Completeions, Study Withard Wals
(i)	In the past approval period, did any participant suffer an unanticipated or serious $\Box$ Yes $\Box$ No adverse event or death?
	s, please attach the Adverse Event log (JREC Template should be used)
	erse 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? <i>If yes, explain</i>
(iii)	Has anything occurred since the last JREC & IRB review that may have altered the risk/benefit relationship? <i>If yes, explain</i>
(iv)	Did you withdraw any participant(s) from your study because of a problem or complication? <i>If yes, explain</i> .
(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?) <i>If yes, explain</i>
Prot	tocol Deviation / Violation Log
In the	e past approval period, did any protocol
	e past approval period, did any protocol
	s, please attach the Protocol Deviation /
	ntion log
5.	Number of Amendments to date
6.	(a) Are you still within the initially applied study duration?
0.	☐ Yes ☐ No
(b)	If <b>No</b> , 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
	·
0	List of DSMB Reports and the Outcomes thereof (if applicable)
8.	List of DSWID Reports and the Outcomes thereof (y applicable)
9.	Positive Outcomes e.g Capacity Building

10. Challer	nges
11. List of	Publications (since last review)
Princiț	oal Investigator's Assurance Statement:
-	pal Investigator's Assurance Statement:  nderstand the JREC's policy concerning research activities and I agree:
-	
I u	to accept responsibility for the scientific and ethical conduct of this research study, to obtain prior approval from JREC before amending or altering the research protocol or implementing
I w 1.	nderstand the JREC's policy concerning research activities and I agree:  to accept responsibility for the scientific and ethical conduct of this research study,

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 <b>must be included</b> in the submission for continuing review:	
Continuing Review Application, complete with signature of PI	
Include the following only <b>if applicable</b> :	
Adverse Event Summary log.	