

KAIRUKI UNIVERSITY

INSTITUTIONAL RESEARCH ETHICS COMMITTEE

FORM KU/IREC 07: CONTINUING REVIEW APPLICATION / ASSESSMENT

Protocol title:	
Protocol No:	
Medical advisor:	
Action requested:	Review for new subject accrual to continue [] Review for enrolled participants follow-up only [] Review for termination of study []
Have there been any amendments since last review?	Yes [] Comment
	No [] Comment
Accrual exclusions	None [] Male [] Female [] Others (Specify)
Impaired participants	None [] Physical [] Mentally [] Both [] Others (Specify)
Have there been any changes in the participant population, recruitment or selection criteria since the last review?	No [] Yes [] Explain
Have there been any changes in the informed consent process or documentation since the last review?	No [] Yes [] Explain
Has any information appeared in the literature or evolved from this or similar research that might affect the Committee's evaluation of the risk/benefit analysis of human subjects involved in this protocol?	Yes [] Comment
	No [] Comment
Have any participants withdrawn for this study since the last approval?	No [] Yes [] Explain
Summary of protocol participants	Accrual ceiling set by the IREC: [] New participants accrued since last review [] Total participants accrued since protocol began []

Have any unexpected complications or side effects been noted since last review?	Yes []	Comment
	No []	Comment
Investigational new drug/device	None [] IND [] IDE [] FDC No: [] Name:..... Sponsor: Holder:	
Ionizing radiation use (X-ray, radioisotopes, etc)	None [] Medically indicated only []	
Have any collaborating sites (institutions) been added or deleted since the last review?	No [] Yes [] (Identify all changes and explanation of changes)	
Changes in medical advisory/investigation?	None [] Deleted ----- -- Added -----	
Have any investigators developed an equity or consultative relationship with a source related to this protocol which might be considered a conflict of interest?	No [] Yes [] (Append a statement of disclosure)	
Signature	Protocol Chairman Date..... IREC Medical Advisor Date Scientific Director Date	
Committee Comment/decision		
Approval	Chairperson, IREC	Date
Completion	Secretary, IREC	Date