HAUREC Form 102: Application For Annual Review (Renewal) Of Research Activity

Note: Apply about two months prior to expiry of approval

Statement Of Policy

It is the policy of the HAUREC (Research and Ethics committee) that 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 subjects. The HAUREC 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.

The Principal Investigator is responsible for timely submission of a continuing review application to prevent any lapse in HAUREC approval. HAUREC regulations do not provide for exceptions to the requirement for continuing review. Therefore, failure by the Principal Investigator to ensure timely review is a serious matter that may lead to suspension or withdrawal of approval. **NO EXTENSIONS CAN BE GRANTED.**

If applying for **re-approval for long-term follow-up or data analysis only**, complete sections A, C,D,E, F, and H only.

A. STUDY INFORMATION			
REC Protocol #		Expiration 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	☐ Self-funded
	☐ 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 all that apply)

Active study

☐ Recruitment/enrollment continues
☐ Accrual complete, research intervention continues
☐ Long-term follow-up
☐ Data analysis only, data collection complete

E. ADDITIONAL INFORMATION

Intervention:

☐ Drug ☐ Device ☐ Genetic study ☐ Tissues

☐ Survey/Questionnaire ☐ Radiation Use ☐ Medical Record Review

☐ Other, Briefly explain _____

Drug/Device name: _____

_____ _____

F. PROGRESS REPORT

1. Enrollment and demographic information: LEAVE NO LINE BLANK

Total number of subjects requested in original HAUREC application: _____

Number of subjects enrolled since last progress report: _____

Total number of subjects enrolled since the start of the study _____

Please report the number of subjects in Uganda in the following categories: (Numbers must add up and make sense. Please check before submitting form)

_____	Currently active in study	_____	Withdrawn from study
_____	Follow-up data collection only	_____	Deaths related to study
_____	Completed intervention and any follow-up	_____	Deaths unrelated to study
_____	Lost to follow-up		

Adverse Events, Complications, Study Withdrawals:

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

If yes, please attach the Adverse Event Report(s) if adverse events not already reported to FOM-REC.

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

Based on your knowledge of the adverse events for this study, do you feel that there is a significant increase in risks to subjects? Has anything occurred since the last REC review that may have altered the risk/benefit relationship? Explain.

Did you withdraw any subject(s) from your study because of a problem or complication? Explain.

Did any subject(s) withdraw themselves from your study? Explain .

Did any problems occur in obtaining or documenting informed consent (i.e., problems with subject understanding, high refusal rate, etc.) Explain.

3. Progress Report:

Please attach a brief summary of findings (preliminary or final) obtained in the study, a summary of recent literature or relevant information, especially information about risks associated with the study. Begin with a 1-2 sentence description of the purpose of the study. **If there are no findings at this time, this should be stated and explained.**

G. AMENDMENT / REVISION REQUEST Complete **ONLY** if Amendment or Revision is requested.

HIGHLIGHT CHANGES TO THE REVISED CONSENT FORM WITH A BRIGHT COLOURED HIGHLIGHTER.

Proposed Amendment(s): List the proposed Amendments and briefly describe the nature of the proposed changes and their rationale. Please attach an amended version of the protocol and/or the Informed Consent if applicable.

Human Subject Population: Has the human subject population changed? If yes, explain. Indicate if there are new performance sites or any changes in selection criteria.

Risks/Benefits: Describe if and how the risks/benefits have changed.

Note: Attach separate sheet if space is not enough.

Principal Investigator's Assurance Statement:

I understand the REC 's policy concerning research involving human subjects and I agree:

1. to accept responsibility for the scientific and ethical conduct of this research study,
2. to obtain prior approval from the Institutional Ethical Review Committee and the UNSCT before amending or altering the research protocol or implementing changes in the approved consent form,
3. to immediately report to the REC and the UNSCT any serious adverse reactions and/or unanticipated effects on subjects which may occur as a result of this study,
4. to train study personnel in the proper conduct of human subjects research,
5. to complete the Continuing Review and Final Report Forms.

Signature of Principal Investigator Date

Write/Typed Name of Principal Investigator

H. 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
☐ Progress Report, attached to application

Include the following only **if applicable**:

☐ Current copy of Consent Form(s) stamped with approval date
☐ Clean copy of Consent Form(s) with revisions if necessary (for new approval stamp)
☐ Informational letters used in place of consent form (cover memo)
☐ Adverse Event Summary Table
☐ Current Approval letters from other foreign sites with REC
☐ Complete protocol including modifications previously approved by the REC (if submitting an amendment or
modification to original protocol)
☐ Recruitment Information (Ads, Web postings, letters etc., if modified from originally approved recruitment materials)
☐ Additional information PI considers important for review by REC