

HAUREC Form 101; Application Form For Researchers Intending To Conduct Health/Medical Research In Uganda

HAUREC FORM 101	For Office Use Only REC/A/2013 FC <input type="checkbox"/> EXP <input type="checkbox"/> XMPT <input type="checkbox"/>
	Date received

This form must be completed by all persons/teams intending to conduct health/medical research in Uganda. Upon completion by the investigator(s) it should be submitted to Hospice Africa Uganda Research and Ethics committee (HAUREC). The required review fee should accompany each application.

Protocol Version Number:.....

APPLICATION FORM CHECKLIST

This checklist was prepared in order to aid investigators in preparing a complete application and to help expedite review by the institutional Review Committee. Your cooperation in completing it will be greatly appreciated.

PRINCIPAL INVESTIGATOR'S NAME:
(SITE PRINCIPAL INVSETIGATOR)

E-mail:

Contact
cell/telephone
number:

- Application form duly completed in duplicate.
- I will submit a soft copy of my proposal at application
- Five copies of complete research protocol in general/funding agency format.
- Five copies of informed consent forms in English and local language of the study population.
- Five copies of Drug Brochure or any supplementary information (if applicable).
- Five copies of Questionnaire being administered during the study (if applicable).
- I have made a copy of this entire application package for my files.
- For clinical trials - I have also submitted an application to NDA (if applicable).

Signature: Principal Investigator (At Site)

Date

Details of Research Team

Name of Principal Investigator (PI)	
Nationality of PI	
Current Qualifications	
Academic Title	
Institution & Dept.	
Postal address	
E-mail address	
Telephone No.	
Is this research expected to lead to the award of a higher degree? (Yes/No)	
If yes, what degree?	
University/Institution where registered	

Co-investigators Names/Supervisors	Qualifications	Institution/Department

Details of the Proposed Research

Title of proposed research.	
Proposed Starting & Ending Dates	
Performance site(s) in Uganda	
Performance sites (outside Uganda)	
Total number of study investigators	
Budget (state currency)	
Name and address of Funding agency:	
Status of funding :	a)Submitted for funding <input type="checkbox"/> b)Pending <input type="checkbox"/> c)Funded <input type="checkbox"/> d)self <input type="checkbox"/>
Beginning & Ending Dates of Funding	

Collaborating Institutions

No	Name of Institution	Institutional Code
2 nd		
3 rd		
4 th		
5 th		

<p>Population: Proposed inclusion criteria (Check all that apply)</p> <p>Males <input type="checkbox"/></p> <p>Females <input type="checkbox"/></p> <p>Vulnerable Groups</p> <p>Foetuses <input type="checkbox"/></p> <p>Children (Under 12 years of age) <input type="checkbox"/></p> <p>Adolescents (12 - 17 years) <input type="checkbox"/></p> <p>Pregnant women <input type="checkbox"/></p> <p>Elderly (over 65 years) <input type="checkbox"/></p> <p>Prisoners <input type="checkbox"/></p> <p>Cognitively impaired <input type="checkbox"/></p> <p>Hospital patients <input type="checkbox"/></p> <p>Refugees <input type="checkbox"/></p> <p>Institutionalized <input type="checkbox"/></p> <p>Other <input type="checkbox"/></p>	<p>Type of study (<i>check all that applies</i>)</p> <p>Cross-sectional/Survey <input type="checkbox"/></p> <p>Secondary data <input type="checkbox"/></p> <p>Program/Project evaluation <input type="checkbox"/></p> <p>Clinical community trial <input type="checkbox"/></p> <p>Case control <input type="checkbox"/></p> <p>Longitudinal study <input type="checkbox"/></p> <p>Record review <input type="checkbox"/></p> <p>Course activity <input type="checkbox"/></p> <p>Other (specify)</p>
<p>Consent Process (<i>Check all that applies</i>)</p> <p>Written : <input type="checkbox"/> Oral : <input type="checkbox"/> English : <input type="checkbox"/> Local Language : <input type="checkbox"/></p> <p>Other : <input type="checkbox"/> (Specify)</p>	

Proposed sample size:.....

Reading level of consent document :

Primary Secondary Tertiary Other
(Specify).....

Determination of Risk *(Check all that applies)*

Does the research involve any of the following	YES	NO
Human exposure to ionizing radiation	<input type="checkbox"/>	<input type="checkbox"/>
Human genetics	<input type="checkbox"/>	<input type="checkbox"/>
Stem Cells	<input type="checkbox"/>	<input type="checkbox"/>
Fetal tissue or abortus	<input type="checkbox"/>	<input type="checkbox"/>
Investigational new drug	<input type="checkbox"/>	<input type="checkbox"/>
Investigational new device or technique (e.g. therapeutic, diagnostic)	<input type="checkbox"/>	<input type="checkbox"/>
Existing data available via public archives/sources	<input type="checkbox"/>	<input type="checkbox"/>
Existing data not available via public archives	<input type="checkbox"/>	<input type="checkbox"/>
Observation of public behavior	<input type="checkbox"/>	<input type="checkbox"/>
Is the information going to be recorded in such a way that subjects can be identified	<input type="checkbox"/>	<input type="checkbox"/>
Does the research deal with sensitive aspects of the subjects behaviour, sexual behavior, alcohol use or illegal conduct such as drug use	<input type="checkbox"/>	<input type="checkbox"/>
<u>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</u>	<input type="checkbox"/>	<input type="checkbox"/>
Could the information recorded about the individual if it became known outside of the research, damage the subjects financial standing, reputation and employability?	<input type="checkbox"/>	<input type="checkbox"/>

- 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.

- Do any of the participating investigators and or their immediate families have conflict of interest with the sponsor of the project or the manufacturer or owner of the drug or device under investigation or serve as a consultant to any of the above?
YES NO (If yes, please submit a written statement of disclosure to the Chairman, HAUREC)
-

RESEARCH PROPOSAL SUMMARY

It is the REC requirement that the composition of the Institutional Review committee (IRC) include individuals with varied backgrounds and education. Investigators are therefore required to attach four(4) copies of a 2-3 page (maximum 4 pages) Research Proposal Summary using the headings provided below in terminology that is understandable across disciplines.

1. RESEARCH QUESTION TO BE ADDRESSED BY THIS PROPOSAL

2. 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, selection and exclusion of subjects, gender. 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.
- Does the study involve any special populations: Subjects will include minors, fetuses, abortuses, pregnant women, prisoners, mentally retarded, mentally disabled, or none of the above.
- 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 SOM-REC 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 HAUREC
- 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 National Drug Authority (NDA) and may not conduct your study without the approval of both the NDA and the SOM-REC. You are also required to complete the relevant part in this application titled " Studies involving the testing of drugs and medical devices".

- Methods for dealing with adverse events
- Methods for dealing with illegal, reportable activities (e.g child abuse)

4. RISKS / BENEFITS TO SUBJECTS

- Highlight 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.)
- Highlight 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.

5. COMPENSATION/REIMBURSEMENT

- 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.

6. 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 (please request for guidelines for implementing informed consent from the HAUREC Offices).
- 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 HAUREC).

7. 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

8. 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?

1. COLLABORATIVE AGREEMENTS

- Provide letters of approval from collaborating institutions' IRCs and from other local IRCs from other sites.

2. INTENDED USE OF RESULTS

- Include plans for dissemination and utilization of study results

1. OTHER INFORMATION:

- Any other information.

Please note : Attach **Five Copies** of the full research proposal. The full proposal should include the following: Title, objectives, background and literature review, methodology (to include research design, subjects and methods, ethical considerations, timetables etc. references, budget etc . Investigators may submit the full proposal in the funding agency format as long as it covers the above headings.

Please also attach copies of **curriculum vitae** for the Principal Investigators and all Co-investigators. The CVs should include the following: Name, Postal address, Employers name and address, Qualifications, Present Position, past research experience (relevant)

and Published Papers (relevant). Principal Investigators or co-investigators who would have already submitted their CVs during the current year are exempted from this requirement.

STUDIES INVOLVING THE TESTING OF DRUGS AND DEVICES

Drug / Device Information Form

Provide dossier or brochure of investigational drug/device

Signature Assurance Sheet

Principal Investigator's Assurance Statement:

I certify that the information given by me is correct to the best of my knowledge; I am familiar with and understand HAUREC's policy concerning research involving human subjects (CIOMS Guidelines or Helsinki Declaration) 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 HAUREC as well as the UNCST before amending or altering the research protocol or implementing changes in the approved consent form;
3. To immediately report to the HAUREC and the UNCST 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 (if applicable).
5. To submit the final study report to HAUREC using a standard form.

Signature	Date
Print name	
Signature of Co-investigator	Date
Print Name	

SUBMIT APPLICATION PACKAGE TO HAUREC OFFICES (The entire application package includes the application form, research proposal summary (2-3 pages), full research proposal (even in funding agency format), consent form and other relevant documents).