UGANDA CANCER INSTITUTE RESEARCH AND ETHICS COMMITTEE

REC Form 101

APPLICATION TO CONDUCT RESEARCH THAT INVOLVES HUMANS AS SUBJECTS

This form must be completed by all persons/teams intending to conduct research that involves humans as research participants in Uganda. Upon completion by the investigator(s) it should be submitted to Uganda Cancer Institute Research and Ethics committee office (UCIREC). Evidence of payment of the required registration fee should accompany each application (Please check on the http://www.uci.or.ug/ for the fees structure and banking details).

Protocol Version Number: ……..

Please indicate type of review category that you would prefer for the submission you have made

☐ Full Board review ☐ Expedited

APPLICATION FORM CHECKLIST

This checklist was prepared in order to aid investigators in preparing a complete application and to help expedite. Please append your signature on each page of the application form.

a) Principal Investigator… ……..
b) Address……
c) Email …….
d) Telephone/mobile contact……

SECTION A: SUBMISSION REQUIREMENTS:

☐ The application form duly completed in duplicate.
☐ A soft copy of the application package should be sent to: *ucirec@uci.or.ug* before handing in the hard copy
☐ Fourteen copies of completed research protocol in general/funding agency format.
☐ Fourteen copies of Research summary
☐ Fourteen copies of each type of informed consent form in English and local language of the study Population
☐ Copies of Drug Brochure or any supplementary information (if applicable)
☐ Fourteen copies of Questionnaire being administered during the study (if applicable)
☐ A copy of Application to NDA (For clinical trials – if applicable)
☐ International/collaborating IRB approvals (if applicable)
☐ 4 copies of Curriculum vitae of each of the study investigators.

NOTE: keep a copy of the entire application package on your file.

SECTION B: DETAILS OF SUBMISSION REQUIREMENTS

Table 1: Profile of Investigators

Name of Principal Investigator (P.I)		
Nationality of P.I		
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 above, what degree?		
University/Institution where registered		
Total number of study investigators		
Details of co-investigators		
Co-investigator's Names	**Qualifications**	**Institution/Department**
Supervisors (Students only)		

Table 2: Details of the Proposed Research

Title	
Proposed Starting & Ending Dates	
Performance site(s) in Uganda	
Performance sites (outside Uganda)	
Budget (state currency)	
Name and address of Funding agency:	
Status of funding :	a)Submitted for funding ☐ b)Pending ☐ c)Funded☐ d)self ☐
Beginning & Ending Dates of Funding	

Table 3: Collaborating Institutions

No	Name of the Institution	Institution code
1.		
2.		
3.		
4.		

SECTION C: ETHICAL CONSIDERATION

CONSENT DOCUMENTS:

The number of consent form types | | |

Details about the consent documents:

Type of consent:	Pages	Languages (specify per consent)	Target group for consent

Determination of Risk *(Check all that applies)*

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

- **Do you consider the proposed research**
  - (i) greater than minimal risk ☐
  - (ii) minimal 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 ☐ **(If yes, please submit a written statement of disclosure to the UCIREC).**

NO ☐

SECTION D: RESEARCH PROPOSAL SUMMARY

The Investigators should submit a maximum 4 pages Research Proposal Summary using the headings provided below in terminology that is understandable by scientists and non-scientists.

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 the study.

3. METHODS

- Study design and rationale for that design. Explain how the study will be conducted.
- 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 UCI-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 the UCI REC.

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

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.

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.

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 UCIREC Office).
- 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 five years after the completion of the investigation, unless otherwise stipulated by the UCIREC).

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

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?

COLLABORATIVE AGREEMENTS

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

INTENDED USE OF RESULTS

- Include plans for dissemination and utilization of study results

OTHER INFORMATION:

- Any other information.

Please note : 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.

For studies involving the testing of drugs and devices provide drug / device information form (Provide dossier or brochure of investigational drug/device).

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-

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 the REC'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 the UCIREC 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 UCIREC 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 the UCIREC using a standard form.

Principal Investigators'	**Primary ; Co – Investigators'**
Signature :	Signature:
Print Name :	Print Name:

SUBMIT APPLICATION PACKAGE TO UCIREC OFFICE AT THE UGANDA CANCER INSTITUTE

OFFICIAL USE ONLY

Check for the following at receipt of the application:

☐The application form should be duly completed in duplicate.
☐Ask if a soft copy of proposal has been sent to the REC email
☐Fourteen copies of complete research protocol in general/funding agency format.
☐Fourteen copies of Research summary
☐Fourteen copies of each type of informed consent form in English and local language of the study population.
☐Copies of Drug Brochure or any supplementary information (if applicable)
☐Fourteen copies of Questionnaire being administered during the study (if applicable)
☐A copy of Application to NDA (For clinical trials – if applicable)
☐Dossier or brochure of investigational drug/device (studies involving the testing of drugs and devices
☐International/collaborating IRB approval(s)

NOTE: Ask if the investigator has kept a copy of the entire application package on file.

Comment:

(i) ☐Application Submission requirements are complete
(ii) ☐Application Submission requirements are incomplete

If Incomplete document action taken and advise given to the investigator and the response
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Name	**Signature:**	**Date**

REC staff that received application