SCHOOL OF HEALTH SCIENCES RESEARCH AND ETHICS COMMITTEE (Mak-SHSREC COLLEGE OF HEALTH SCIENCES	**For Office Use Only** **REC C/A/2011-** FC ☐EXP☐ XMPT☐
REC FORM 101	**Date received** ……

APPLICATION TO CONDUCT HEALTH/MEDICAL & SOCIAL RESEARCH

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 the School of Health Sciences Institutional Review Board and Ethics committee (MAK-SHS-IRB). Upon completion of the relevant section by the IRB, the form should be submitted to the Research Administrator, School of Health Sciences Institutional Review Board and Ethics Committee Makerere University College of Health Sciences P. O Box 7072, Kampala. The required registration fee should accompany each application. IRB fee should be deposited to Makerere University School of Health Sciences Research Account in the School of Health Sciences Accounts office

Protocol Version Number:…….

APLICATION FORM CHECKLIST

This checklist was prepared in order to aid investigators in preparing a complete application and to help expedite review by the Ethical 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 REC101 duly completed in duplicate. (2 copies)

☐ Two (2) copies of CVs for all investigators

☐ Twelve (12) copies of complete research protocol in general/funding agency format. (Indicate version number & date)

☐ Four (4) copies of Research summary

☐ Two (2) copies of Letter(s) of support/collaboration

☐ Two (2) copies of International/collaborating IRB approval(s)

☐ Twelve (12) copies of informed consent forms in English and the translated version in local language of the study population.

☐ Twelve (12) copies of the Assent form(s) English &Translated version (if applicable)

☐ Twelve (12) copies of the Consent/assent for future storage of specimens, English & Translated version (if applicable)

☐ Twelve (12) copies of surveys/Questionnaires/instruments/ being administered during the study (if applicable).

☐ Twelve (12) copies of the Parental consent form, English & Translated version (s) (if applicable)

☐ Twelve 12 copies of the Screening tool (if applicable)

☐ Twelve (12) copies of Drug Brochure or any supplementary information (if applicable).

☐ 12 copies of Departmental minutes (A must by Masters students)

☐ 1 copy Evidence of payment of research review fees (if applicable) please refer to the charge structure

☐ 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).

☐ Submitted electronic copy or a soft copy of the WHOLE package to healthsciences.irb@gmail.com **(A MUST).**

---------- ----------

Signature: Principal Investigator (At Site) Date

Details of Research Team

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, 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 ☐ b)Pending ☐ c)Funded☐ d)self ☐
Beginning & Ending Dates of Funding	

Collaborating Institutions

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

Population: Proposed inclusion criteria
(Check all that apply)

Males ☐
Females ☐

Vulnerable Groups

Foetuses ☐
Children (Under 12 years of age) ☐
Adolescents (12 – 17 years) ☐
Pregnant women ☐
Elderly (over 65 years) ☐
Prisoners ☐
Cognitively impaired ☐
Hospital patients ☐
Refugees ☐
Institutionalized ☐
Other ☐

Type of study *(check all that applies)*

Cross-sectional/Survey ☐
Secondary data ☐
Program/Project evaluation ☐
Clinical community trial ☐
Case control ☐
Longitudinal study ☐
Record review ☐
Course activity ☐
Use of stored samples ☐

Other (specify) ……..

☐ **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	☐	☐
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**
  - 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 of the SHS-REC)

RESEARCH PROPOSAL SUMMARY

It is the IRB requirement that the composition of the Institutional Review Board (IRB) include individuals with varied backgrounds and education. Investigators are therefore required to attach four(4) copies of a <u>2-3</u> <u>page</u> (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 <u>briefly</u> 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 SHS-REC for review and approval <u>prior</u> 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 MAKSHS-IRB.

- 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 SHS-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)

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 MAK-SHS-IRB 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 MAK-SHS-IRB).

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 : Attach **12 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 the IRB'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 Mak-SHS-IRB 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 Mak-SHS-IRB 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 Mak-SHS-REC using a standard form.

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

SUBMIT APPLICATION PACKAGE TO THE DEAN'S OFFICE Mak-SHS-IRB 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).

****

SCHOOL OF HEALTH SCIENCES INSTITUTIONAL REVIEW BOARD AND ETHICS COMMITTEE REVIEW AND ENDORSEMENT REQUIRED

Statement from the Institutional Ethical Review Board:

The IRB will only accept for review and approval research proposals that have been found both scientifically and ethically acceptable in accordance with the Guidelines on Institutional Ethical Review Boards.

We the **Institutional Ethical Review Committee** established by

……..

(Name of Institution conducting the research/in which the research is to be conducted)

do certify that we have reviewed the research proposal titled

……

……..

Submitted by

……..

We attest to the scientific and ethical merit of this study and the competency of the investigator(s) to conduct the project and do hereby recommend the proposal to the UNCST for approval.

SIGNATURES

	Signature Ethics Committee representative			Date	
	Name (Please Print)				
	Signature: Head, IRB & Ethics Committee (or other authorized signatory)				
	Name (Please Print)				

Contact Tel. Number ***:……..……...***

E-mail address ***: ……***

OFFICIAL STAMP OF INSTITUTION

****Institution includes Universities, Hospitals, Research Institutes or Companies.***