NIGERIAN INSTITUTE OF SCIENCE LABORATORY TECHNOLOGY
FEDERAL MINISTRY OF SCIENCE, TECHNOLOGY AND INNOVATION
NATIONAL SECRETARIAT, SAMONDA, IBADAN

Principal Investigator Affix recent Passport

APPLICATION FOR LABORATORY RESEARCH ETHICAL APPROVAL

APPLICATION FORM NUMBER: ……

This form Should be completed and returned to the Registrar of the Institute, with the form application fees (₦5,000) and photocopies of all relevant documents

Instructions: All applications for Laboratory ethics approval should be submitted using this form. The Principal Investigator is required to ensure the information provided is accurate and will sign on this form to indicate that he/she approves the content. The information provided in this form is expected to be complete and adequate for reviewers to make a decision on the final disposition of the proposal.

The Application Form must be TYPED in capital and lower case or Handwritten. The forms should be completed in full and relevant signatures must be provided. Should this not be done, the evaluation process will not commence. **An electronic version must also be submitted** inform@nislt.gov.ng.

Title of Project		
Name of the Principal Investigator (PI) based in Nigeria		
Names of other investigators (PIs and Co-PIs)		
Qualifications of PI		
Position		
Institution and Department/Unit		
Other co-investigators at the PI institution		
NISLT No. (Members) or representative		
Signature of the PI		
If Research student: Name, signature and approval of Supervisor (include approval letter)	Name:	Signature:
Contact details for correspondence (include the name of contact if different from the PI)	Physical: Postal: Tel: Email:	
If this study involves more than one institution, name the overall study PI, institution and contact address		
Name of other institutions involved in the study if this study involves more than one institution		

Purpose of Research *(Check **X** in the relevant boxes - double click on check box)*	**Not for degree purposes** ☐ **Postgraduate: degree/diploma (state which)** ☐ Name of degree/diploma: **Undergraduate: degree/diploma (state which)** ☐ Name of degree/diploma: **Professional Awards**: (State which) ☐
Nature of Research *(Check **X** in the relevant boxes - double click on check box)*	Retrospective study ☐ Prospective study ☐ Longitudinal study ☐ Cross-sectional study ☐ Audit ☐ Review of records ☐ Behavioural study ☐ Anthropological or sociological study ☐ Operational study ☐ Observational study ☐ Development and/or testing of an educational method(s) ☐ Action research aimed at improving educational practices ☐ Quantitative methods to be used ☐ Qualitative methods to be used ☐ Historical study ☐ Laboratory Experimental study ☐ Mixed methods to be used ☐ Other (describe) ☐
Describe further if necessary	

Does this study involve the taking of blood and/or any other biological samples?: Yes ☐ No ☐ NA ☐
Does this study involve shipment of biological samples outside Nigeria?: Yes ☐ No ☐ NA ☐ If Yes, Please attach Material Transfer Agreement
Does this study going to involve data sharing/transfer outside Nigeria?: Yes ☐ No ☐ NA ☐ If Yes, Please attach Data sharing/transfer agreement
Is this an externally sponsored research?: Yes ☐ No ☐ NA ☐ If Yes, Please attach ethics approval letter from foreign ethics committee
Provide the scientific background, study design and objectives and hypotheses of the research. Max 300 words (attach sheet)
State the intended value of the project or rationale. Why it is important to conduct this study in Nigeria? Provide relevant references as appropriate. Max 200 words
State the total duration of the project, and where it will be undertaken in Nigeria (and also in other countries if appropriate)

Provide evidence (such as commitment/endorsement letter) to show that local government officials in the region(s)/district(s) where the proposed research will be conducted have been informed about this study. IF THIS HAS NOT BEEN DONE, describe how you plan to achieve this BEFORE the study starts
Specify the number of the study participants, with scientific justification for sample size, age, gender
Specify recruitment methods, inclusion and exclusion criteria and study end points
Specify data collection procedures, including interviews and sample collection, involving human participants with brief details of actual methods. Attach copies of questionnaires and other data collection tools in English and French(If applicable) 400 words
If applicable, describe procedures to be used to process, store and test biological samples (e.g. blood, genital swabs, urine, etc).
If samples will be taken overseas, are there samples which will be left in Nigeria? Describe procedures to be used in their shipping, storage and when will be destroyed. Indicate which institution or laboratory samples will be analysed. Please note that before samples are shipped outside Nigeria, Custom clearance is required.
Is the technology required for analysis of samples available in Nigeria? Yes ☐ No ☐ NA ☐ If YES, please describe why are samples being taken outside the country
Would local scientist(s) (Nigerians) be involved in sample analysis? Yes ☐ No ☐ NA ☐ If YES describe her/his involvement, and if NOT please explain what are the strategies for technology transfer
Specify data management procedures and methods to be used during data analysis
If data will be taken overseas, please describe why are being taken outside the country.
Describe the potential risks, discomfort, distress or hazards that research participants may be exposed to (these may be physical, biological and/or psychological). What precautions will be taken to reduce risks and ensure participants' safety?
Describe potential benefits for the participants and the population where they come from. Are there direct benefits for the people of Nigeria and/or other countries?
Specify how confidentiality of the study participants and data collected will be maintained.

Where will the research be carried out? *(Please furnish name of Laboratory /institution and particular department*)	

Requirements for Participant Information Sheet *(Check **X** in the relevant boxes - double click on check box)*
Describe steps to be taken to minimise coercion/undue influence during the consent process
Describe how you are going to assess comprehension of the information provided during the consent process
• Consent will be only verbal ☐ • Consent will be only written ☐ • Consent will be written or verbal (depending on participant's literacy) ☐

• Informed consent is not necessary ☐
State why not:
Request waiver for consent due to nature of study ☐
Please state why?:
Assent / Guardian form must be attached. Age range of patients/participants/controls: If under 21 years, from whom will consent be obtained?
State the experience of the PI and co-investigators in the study in the field concerned, and what their role will be on the project
Please describe how project staff (PI and other staff) will be trained on the protection of study participants in research. In case already trained attach certificate
When applicable, state what medical supervision is available to the participants
Describe the facilities available to support the successful conduct of the proposed research study, i.e.; office space, equipped laboratories.
If this is a clinical/intervention trial of a medicine, device, biologic/vaccine, or any other form of treatment or intervention, please respond to the following questions:
What phase clinical trial is being conducted?: Phase I ☐ Phase II ☐ Phase III ☐ Phase IV (post marketing) ☐ Other ☐ If OTHER specify.
Is it a multicentre trial? Yes ☐ No ☐
Is the clinical trial registered with a clinical trials registry? Yes ☐ No ☐ If YES name it
Have adequate animal toxicity and teratogenicity trials been carried out? Yes ☐ No ☐
What is the justification for using a control arm?
Does the control group receive the standard therapy? Yes ☐ No ☐ NA ☐
Are all participants treated equally? If NOT explain.
What is the procedure for dealing with adverse events?
What is the procedure for reporting adverse events?
Will the sponsoring agency provide the drug / device to the patient till it is marketed in the country? Yes ☐ No ☐
What are the criteria for termination of the trial?

Is there provision for insurance of the trial participants? Explain Yes ☐ No ☐
How does the trial comply with Good Laboratory Practice (GLP)?
Does this trial involve testing a new drug, vaccine or medical device which is not registered in Nigerian? Yes ☐ No ☐
If this trial involves testing a new drug, vaccine or medical device, please attach the investigator brochure? If there is no investigator brochure, please explain the reason
What will be offered to the control arm?
Please confirm that *NISLTLREC* approval will be processed before data collection begins. Yes ☐ No ☐
Is there a Data Monitoring & Safety Committee in place? Yes ☐ No ☐ If NO, please explain reasons
If the intervention to be tested is found to be effective, describe plans to make it available to the participants and other people after the end of the trial
Have you obtained a certificate insurance cover for study participants locally Yes ☐ No ☐ If YES please attach & If NO please describe how this will be obtained
Please give details of the funder.
Please give details of research sponsor. This is not necessarily the funding body. The sponsor is responsible for the initiation and management of the study. All clinical trials should have an identified sponsor.
Please state any other thing that you think could be useful in the evaluation process

OFFICIAL REMARK

FOR OFFICIAL USE ONLY

Eligible ☐ Not Eligible ☐

If not Eligible state reason(s): ……..…….....
…….....
…….....

Receipt No.: ……..……...

Application form submission Date: ……..

Date Registration: ……

Form Processed by: ……

Final Remarks: ……

For further information and enquiries, please contact the Director-General/Registrar/Chief Executive Officer
Nigerian Institute of Science Laboratory Technology
National Secretariat Samonda, P.O. Box 9764 U.I. Post office, Ibadan
Tel: 08062117814, 08030787747, 07087978055
E-mail: inform@nislt.gov.ng; enquiry@nislt.gov.ng
Website: www.nislt.gov.ng