

 UNIVERSITY OF SAINT LOUIS Tuguegarao City, Cagayan	UNIVERSITY OF SAINT LOUIS- UNIVERSITY RESEARCH ETHICS BOARD (USL-UREB)	Document No. FRM-URB-2.2 Revision No. 00 Effectivity Date November 3, 2020 Page No. 1 of 4
	RESEARCH PROTOCOL APPLICATION FORM	

SECTION I: APPLICATION INFORMATION

USL-UREB Code: <i>(To be filled out by/ assigned by the USL-UREB Secretariat)</i>		
Type of Submission	<input type="checkbox"/> Initial Review <input type="checkbox"/> Resubmission <i>version no:</i> _____	
Date of Submission:		
Study Category:	<input type="checkbox"/> Research involving human participants <input type="checkbox"/> Research involving animal subjects <input type="checkbox"/> Others, please specify: _____	
Category of Investigator/s:	<input type="checkbox"/> Faculty Member <input type="checkbox"/> Non-Teaching Personnel <input type="checkbox"/> College/ Undergraduate Student <input type="checkbox"/> Graduate Student <input type="checkbox"/> Others, please specify: _____	
Submission Route:	<input type="checkbox"/> Post <input type="checkbox"/> E-submission <input type="checkbox"/> In-person	
Submitted by:		
	Study Designation:	

SECTION II: STUDY INFORMATION


Study Title:		
Purpose of the Study:	<input type="checkbox"/> Academic Requirement (Thesis, Dissertation, Training requirement) <input type="checkbox"/> Independent Research Work <input type="checkbox"/> Requirement for Promotion/ Professional Advancement <input type="checkbox"/> Multi-institutional Collaboration <input type="checkbox"/> Others, specify: _____	
Endorsing Unit	<input type="checkbox"/> USL Academic Departments <ul style="list-style-type: none"> <input type="checkbox"/> School of Accountancy Business and Hospitality <input type="checkbox"/> School of Education, Arts and Sciences <input type="checkbox"/> School of Engineering, Architecture and Information Technology Education <input type="checkbox"/> School of Health and Allied Sciences <input type="checkbox"/> School of Graduate Studies and Continuing Professional Development <input type="checkbox"/> Basic Education Unit (Elementary, Junior, Senior High School Departments) <input type="checkbox"/> USL Non-Academic Units, please specify office: _____ <input type="checkbox"/> Other Institutions	
Study Duration (in months):		
Study Site:	<input type="checkbox"/> Within the University	

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	<input type="checkbox"/> Outside USL with local IRB <input type="checkbox"/> Outside USL without local IRB <input type="checkbox"/>
Source of Funds:	<input type="checkbox"/> Internal Funding (Funds from within the university like grants/ incentives or research loads) <input type="checkbox"/> External Funding (Funds from outside the university) <input type="checkbox"/> Government Agencies <input type="checkbox"/> Non-government organization <input type="checkbox"/> Personal Funding <input type="checkbox"/> Others, specify: _____
Study Budget: <i>(NOTE: This refers to line item amounts. However, if a separate budget sheet is available, just indicate total amount and attach budget sheet)</i>	
Was this protocol previously reviewed or approved by other ethics review sites?	<input type="checkbox"/> No <input type="checkbox"/> Yes <ul style="list-style-type: none"> • Name of IRB/REC: _____ • Date of Approval: _____ • Date of Expiration of Ethics Approval: _____
Use of special populations or vulnerable groups:	<input type="checkbox"/> Children (under 18) <input type="checkbox"/> Indigenous People <input type="checkbox"/> Elderly <input type="checkbox"/> People on welfare/social assistance <input type="checkbox"/> Poor and unemployed <input type="checkbox"/> Patients in emergency care <input type="checkbox"/> Homeless persons <input type="checkbox"/> Refugees or displaced persons <input type="checkbox"/> Patients with incurable diseases <input type="checkbox"/> Others, specify: _____ <input type="checkbox"/> Not applicable

SECTION III: STUDY PROTOCOL SYNOPSIS

Technical Synopsis	<i>The synopsis should include the following:</i> <ul style="list-style-type: none"> • Objectives/Expected output • Research design • Sampling design, sample size • Inclusion criteria, exclusion criteria, withdrawal criteria • Data collection plan • Specimen collection and processing plan (including plans for specimen storage and duration of storage) • Data analysis plan (including statistical basis for design, as applicable) • Rationalization for choice of study site (including capacity of site to address known risks of study protocol, such as availability of equipment and facilities, as applicable)
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	<i>Please cross reference information indicated here with statements provided in the informed consent.</i>
Ethical Considerations	<i>This should be stated in the study protocol, and should include the following (as applicable)</i> <ul style="list-style-type: none"> • Protection of privacy and confidentiality of research information including data protection plan • Vulnerability of research participants • Risks of the study (including social risks) • Benefits of the study • Patient-related compensations/reimbursements/entitlements • Informed consent process and recruitment procedures • Terms of reference of collaborative study (as applicable, such as intellectual property agreements and similar concerns) • Terms of available study-related insurance

SECTION IV: PRINCIPAL INVESTIGATOR INFORMATION

Principal Investigator:									
Birthday:									
Institutional Address (if outside USL):									
Mobile Number:									
Email Address:									
Other ongoing studies:	<ul style="list-style-type: none"> • Title 1: _____ • Title 2: _____ • Title 3: _____ • Title 4: _____ 								
Other Investigators: <i>(add additional rows as applicable)</i>	<table border="1" style="width: 100%;"> <thead> <tr> <th style="width: 70%;">Name</th> <th>Task Description</th> </tr> </thead> <tbody> <tr> <td> </td> <td> </td> </tr> <tr> <td> </td> <td> </td> </tr> <tr> <td> </td> <td> </td> </tr> </tbody> </table>	Name	Task Description						
Name	Task Description								
Declaration of Conflict of Interest by Principal Investigator:	<input type="checkbox"/> I have no conflict of interest in any form (financial, proprietary, professional) with sponsor, the study, Co-Investigators, or the site <input type="checkbox"/> I have personal/family financial interest in the results of the study. Please state the nature of interest: _____								
PI Signature:									

SECTION V: SCIENTIFIC/ TECHNICAL REVIEW APPROVAL

<i>This section should be signed by the Chair/Head of the Scientific/Technical Review committee/office that reviewed the scientific soundness of the study and issued the appropriate approval. Alternatively, results of Scientific/Technical Review disposition may be appended to this application, instead of completing this section, provided that the information required below had been appropriately addressed.</i>	
STUDY PROTOCOL TITLE:	
Principal Investigator:	
I confirm that the (NAME OF RESEARCH CENTER/ OFFICE) has reviewed and approved the following study protocol-related information: Objectives/Expected output supported by literature review; overall research design; sampling design, sample size, Inclusion/exclusion/ withdrawal criteria; data collection plan and specimen collection, processing, and	

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storage as applicable; data analysis plan including statistical design/framework, as applicable.

Issuing Research Center/ Committee:	
Head of Committee/Center:	
Signature:	
Date of Signature:	

SECTION VI: INSTITUTIONAL ENDORSEMENT

This section should be signed by the head of unit (administrative authority legally empowered to sign on behalf the unit such as Dean, Director, Head of Office) of the Principal Investigator. This section is required only for initial submission, provided there are no changes in study protocol information below.

STUDY PROTOCOL TITLE:	
Principal Investigator:	

I confirm that I have read this Application and that the research will be implemented under the oversight of this Department/Institution in accordance with the conditions of approval by the USL-REC. I also confirm that the Principal Investigator has a regular appointment in this institution.

Issuing Unit/ Department:	
Head of Unit/ Department:	
Signature:	
Date of Signature:	

Received by:

Signature over Printed NameDate (mm/dd/yyyy)

This protocol/ proposal is recommended for:

- Expedited Review Full Board Review Review Exemption

Recommended by:

USL-UREB Chairperson
Date Signed: