NORTHERN CARIBBEAN UNIVERSITY
OFFICE OF RESEARCH & GRANTS
INSTITUTIONAL REVIEW BOARD (IRB)
HUMAN SUBJECTS APPLICATION FORM

***DO NOT* DELETE OR CHANGE ANY SECTION OF THIS FORM.**
Any evidence of tampering with the format or contents, other than completing the appropriate areas, will be seen as an attempt at dishonesty and will be treated as such.

There are five (5) categories of approval for which you may apply:

- ***Exempt Review*:** Projects that ***DO NOT include human or non-human vertebrate animal subjects.*** For example, persons in IT working on an algorithm to streamline online entry of data, or persons in Biology working on invertebrate subjects, or persons in religion looking at a manuscript in ancient text.
- ***Expedited Review*:** Projects that require a quick response due to deadlines with grant funding or graduation.
- ***Full Review*:** All projects that are being reviewed for the **first time** fall in this category. Projects seeking funding (NCU faculty/staff ONLY) and have no ethical issues for consideration also fall in this category.
- ***Modification Review*:** In the event that a previously submitted project has been modified, this category would apply.
- ***Renewal Review*:** In the event that the time given for ethics approval has expired (as in the case with **all graduate projects** which are only **approved for only one year from the date of approval**), an application for renewal must be submitted.

You are not required to print the document, **ONLY** the signature page; this should then be sent to the office of research and grants. Proposals should be submitted by the **research coordinator** (**advisor)**, or the **administrative assistants within the colleges or school**. No proposal should be submitted by students. **For student proposals**, before submitting the documents save/name the document using the student's name and ID number. ***For example: Mary Buckingham 17008910 IRB Application***.

Be detailed in your response to the questions. This will provide the board with the necessary information to determine the outcome of your application. Failure to do this will result in delays in processing your application.

Definition of Terms

***Principal Investigator (PI)*:** The person in charge of the research project and is responsible for all activities that occurs therein.

***Co- Principal Investigator (Co-PI)*:** A person who shares in the responsibility of directing the research project.

***Investigator*:** A person tasked with carrying out the research activities on a project.

***Conflict of Interest Disclosure*:** Where an individual has one or more significant financial (or research) interest(s), and where these interests have the potential to taint or impact the conducting or reporting of the current project being executed, a statement outlining this should be included.

***Annotated Budget*:** Include a section named "Annotations" that explains **in detail** how the figures are calculated, so that the reviewer can be convinced of the viability of the project and the preparedness of the researchers to conduct said project. In the event that a project will have no overhead costs associated with it, materials and services being donated should be accounted for and should be listed as budgeted items.

NORTHERN CARIBBEAN UNIVERSITY
INSTITUTIONAL REVIEW BOARD
RESEARCH ETHICS REVIEW APPLICATION FORM
FOR HUMAN SUBJECTS

SECTION 1 GENERAL INFORMATION

Research Project/Thesis/Dissertation Title:

Principal Investigator:

Name

Department Affiliation

Degree

Emphasis

Investigator's Address

Contact: ***Office:*** ***Home:*** ***Cell:***

Email Address:

Signature:

Students fill out the following section:

**Students receive approval for only a year. Subsequently an application for renewal must be submitted.*

i. Is this research part of your graduate thesis/dissertation? Yes ☐ No ☐
ii. Indicate source of funding. NCU ☐ NON-NCU ☐ *Specify:*
iii. Expected Start Date: _____
iv. Expected Completion Date: _____

SECTION 2 RESEARCH TEAM, SITE & FUNDING

- ☐ NCU Faculty
- ☐ NCU Administrator
- ☐ NCU Staff
- ☐ NCU Student
- ☐ Other *(specify)* _____

Co-Investigators:

	Co-Investigator 1	Co-Investigator 2	Co-Investigator 3
Name			
Contact			
Email Address			
Organization			

Research Assistant Information *(if applicable)*			
	Research Assistant 1	**Research Assistant 2**	**Research Assistant 3**
Name			
Mailing Address			
Phone Number			
Email Address			

Site Information

Will the study be conducted at a non NCU site? Yes ☐ No ☐

If "Yes" complete the following for non-NCU site(s). Please affix an additional document if there are more sites than this form allows you to document.

	Site 1	**Site 2**	**Site 3**
Site Name:			
Address:			
Phone Number:			

Please affix documentation which indicates permission to conduct the research at non-NCU sites. These include permission letters.

Collaborative Research Information

- Are other organizations/institutions participating in this research? Yes ☐ No ☐
- Was this proposal submitted to another IRB? Yes ☐ No ☐

If "Yes" please affix a copy of the approval letter.

	Institution 1	**Institution 2**	**Institution 3**
Name of Institution			
Contact Person			
Position			
Contact Number			

Funding Information

- Funding status: Unfunded ☐ Funding applied for ☐ Funded ☐
- Type of Funding: Grant ☐ Fellowship ☐ Internal (NCU) ☐
- Source of Funding: _____
- Award Amount: _____

*Please attach a **detailed annotated** budget*

Declaration by Principal Investigator/Student

By signing or typing my name below, I certify that I have completed the NIH training in Human Research, (https://phrp.nihtraining.com/users/login.php) and I agree to comply with all regulations governing research with human participants. I acknowledge that I am responsible for requesting any modifications to this protocol for review and approval by the IRB prior to implementation.

I agree to report any adverse events immediately to the IRB and to comply with all requests to report on the status of a study if so requested. I agree not to recruit participants or collect data until I receive an approval letter from the IRB granting permission to do so.

Name: _____ **Signature:** _____

Declaration by Dissertation / Thesis Chairs and Co-investigators

I/We agree to uphold the same standards and abide by all regulations as stated above.

Name: _____ Signature: _____

Name: _____ Signature: _____

Name: _____ Signature: _____

SECTION 3 PLEASE COMPLETE FOR HUMAN SUBJECT(S) RESEARCH APPROVAL

Abstract ***(Write a summary of 250 -500 words describing the background, purpose, significance, methodology, and expected outcomes of the project).***

1. Indicate whether this project involves any of the following participant populations/subjects or materials:

- ☐ Economically or educationally disadvantaged participants
- ☐ Cognitively impaired or mentally disabled participants
- ☐ Prisoners
- ☐ Pregnant women
- ☐ Minors (persons under 18)
- ☐ Vertebrate animal(s) (including tissue, fluid etc.)
- ☐ Biological/chemical/radiation hazardous material
- ☐ None of the above
- ☐ Other (*specify)* _____

2. Using non-technical language, describe the research process you will employ. Please outline *in detail* the steps in the research study in order as they will occur after consent has been secured.

3. List and/or describe your sources of data collection/ instruments. Please attach a copy of each to the completed form.

4. Describe the characteristics of the participants, including age range, gender and whether

they belong to any vulnerable population group(s).

5. Describe the process of selecting subjects. Also clearly indicate the number of subjects selected.

6. Describe the benefits of the research to the subjects, where applicable, and the contribution to the body of knowledge.

7. Are there any risks or disadvantages for the subjects? How will these be minimized and monitored?

8. Detail the steps which will be used in the informed consent process.

9. How will the subject's privacy and confidentiality be protected?

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Approval granted after:		***Approval denied after:***	
Exemption Review	☐	Exemption Review	☐
Expedited Review	☐	Expedited Review	☐
Full Review	☐	Full Review	☐
Modification Review	☐	Modification Review	☐
Renewal Review	☐	Renewal Review	☐

Name: _____ **Signature:** _____ **Date:** _____

Name: _____ **Signature:** _____ **Date:** _____