UNIVERSITY of the SOUTHERN CARIBBEAN
Royal Road, Maracas, St. Joseph, Trinidad

OFFICE OF RESEARCH AND INNOVATION

INSTITUTIONAL REVIEW BOARD (IRB) APPLICATION FORM

IRB #: USC-RE-REC-001 *(Official Use only)*

All sections of this application MUST be completed before it will be considered for IRB review. Supporting documents (proposed consent form, copy of your proposal, questionnaires, and letters of authorizations) must be submitted with this form. A complete application form and supporting documents must be submitted to the Department of Research and Innovation at least thirty (30) days prior to the start of the study.

SECTION I: GENERAL INFORMATION

1. Principal Investigator (PI)			
First Name:	Last Name:	Telephone:	Email:
_____Yes, I am a Faculty ☐ Staff ☐			
_____Yes I am a student. If so, please provide information about your faculty advisor below.			
First Name:	Last Name:	Telephone:	Email:
Advisor's signature:			
Department:		Program:	

2. Co-Investigators (*If Applicable*)			
First Name:	Last Name:	Telephone:	Email:
First Name:	Last Name:	Telephone:	Email:
First Name:	Last Name:	Telephone:	Email:

3. Research Project
a. Full study title:
Will the research be conducted on the USC campus? _____Yes ____No

If No, please indicate the location(s) of the study and attach an institutional authorization letter as a supporting document:
_____

b. Is this project funded? ____Yes ____No

If Yes, please indicate the source of funding.

____Internal Funding Source: _____

____External Funding Source: _____

c. Type of data used in this project: _____Primary ____Secondary

d. Study Period: Expected start date:_____ Expected completion date: _____

SECTION II: RESEARCH PROTOCOL

4. **Study Summary**- Must be a summary of the study outlining the main aim, rationale, theoretical framework, methods, expected outcomes and potential benefits for individuals or society at large. (Maximum 250 Words)

_____
_____
_____

5. **Objectives** - Indicate the objectives for this study.

_____
_____
_____

6. **Variables** – State and describe the key variables for this study.

_____
_____

7. **Statement of the Problem –**Briefly explain the key issues of this study and the current status of the problem under study, providing evidences from the literature (500 words).

_____
_____
_____

8. **Hypothesis/es & Research Questions -** State the hypothesis and/or research questions for this study.

_____
_____

9. **Methodology**

Many of these questions apply to field/survey research studies. If any of the items are not applicable to your study, indicate N/A.

9A. ***Research Design*** - Describe the research design for this study.

_____
_____
_____

9B. *Subjects/ Controls*

9B i. Indicate the main inclusion/ exclusion criteria for your study population.

_____
_____

9B ii. Indicate the age range of eligible subjects: If not applicable, indicate the rationale.

_____
_____

9B iii. Indicate the sample size of the study and the time (month & year) when the sample selection occurred.

Sample size: _____
Time of sample selection: Month_____Year_____

9B iv. Is sample size justified in the study design? ___Yes ___ No

If no, provide sample size justification.

_____
_____

9C. *Data Collection*

9C i. Describe the data collection methods for this study.

_____
_____
_____

9C ii. State the methods used to ensure reliability and validity of the data collected in this study.

_____
_____

9D. *Data Analysis* - Briefly explain the methods used for data analysis for this study.

_____
_____
_____

SECTION III: ETHICAL ISSUES

10. Recruitment and Consent

Note: Any documents to be viewed by the participants (e.g. recruitment posters/letters, informed consent/assent forms, information sheets, instruments of data collection – questionnaires or interview schedules/guides) must be included with your submission as Appendices with this application.

10A. *Sample Selection & Recruitment Process* - State what sampling methods were used to identify and recruit participants for this study.

Sample Selection:

_____

_____

Recruitment Process:

_____

_____

10B. ***Consent Process***

10B i. Describe the consent process (who will obtain the informed consent, type of consent to be given - written, oral, telephone). Copy of consent form must be included.

_____

_____

10B ii. Indicate if there is a relationship between participants and either of the following:

Person obtaining consent: ___Yes ___No

Investigator: ___Yes ___No

10B iii. If yes, explain the nature of the relationship (e.g. faculty, student employer) and what steps will be taken to avoid the perception of undue influence.

_____

10B iv. Indicate how much time will be given to participants to review the information before asking to give consent.

_____

10C. ***Indicate if the research will involve any of the following:***

__Women of child bearing age
__Children
__Residents of custodial institutes
__Students
__Pregnant women
__Persons with physical vulnerabilities
__Persons with psychological disorders
__ None of the above

11. Risk/Benefit Estimates

11A. ***Potential Benefits to the Participants*** – State if any direct benefits are anticipated to the participants of this study.

Direct benefits anticipated ___Yes ___No

If yes, list Anticipated Benefits to the participant if any.

_____

11B. ***Potential Risks to the Participants***

11B i. Does the study involve any of the following potential risks (injury, discomfort, and inconvenience) to the participant (including psychological factors)?

__ No known risks

__Negligible (*where there is no foreseeable risk of harm or discomfort; and any foreseeable risk is not more than inconvenience)*
__ Low (*where the only foreseeable risk is one of discomfort*)
__ High (*where the risk, even if unlikely, is more than inconvenience, the research is not negligible risk*)

11B ii. Describe the methods to be used to minimize the risk to participants.

_____

12. Payments

12A. ***Will there be any payments involved in this study?*** ___Yes ___No ___N/A

12B. ***If yes, indicate what payment (s) will be provided to the participants or substitute decision makers, if applicable.***

__Reimbursement for expenses incurring as a result of research (specify the amount e.g. travel, meals)
_____
__Gifts for participation (state the approximate value) _____
__Compensation for time: Amount: _____ (Provide justification if compensation for time will be provided)
_____
__Other forms of compensation _____

13. Potential Conflicts of Interest

If any of the conflicts listed below apply to any of the investigators involved in the research study or any member of their immediate family, append a letter to the Chair of the IRB detailing these activities and how they will be managed. Disclose all contracts and any conflicts of interest (actual, apparent, perceived, or potential) relating to this project.

__Function as an advisor, employee, officer, director or consultant for the study sponsor
__Have direct or indirect financial interest in the device or technology employed in this research study (including patents or stocks)
__Not applicable

14. Publication/Dissemination of Results

14A. ***Indicate how the results will be communicated to participants and other stake holders (e.g., advocacy groups, scientific community). Tick all that apply.***

__ Individual debriefing at end of test session
__ Group debriefing
__ Letter of appreciation at end of study
__ Conference
__ Publication
__ Other (Specify):_____
__ No plan

14B. ***If no plan is in place provide justification.***

_____

SECTION IV: PRIVACY AND CONFIDENTIALITY

15. Identification of the Study Participants

15A. ***Indicate how study participants will be identified on data collection forms (e.g. study number, initials).***

_____

_____

15B. ***Indicate if any information that could potentially identify study participants will be disclosed outside of the institution (e.g. names, initials, DOB, ID#).***

___Yes ___No

If yes, justify and describe how this information will be transferred and any security measures to be used (e.g., secure network up load or download).

_____

16. Data Storage - Indicate how data will be stored for this study.

__Computerized files (specify) server__ desktop__laptop__
__Audio recording
__Hard copy
__Video tape
__Other (specify) _____

17. Safeguards to Protect Confidentiality and Security of Data - Describe the safeguards to protect the confidentiality and security of the data, including any physical and technical safeguards for this study (e.g. data will be stored in a locked and secure area, data will be stored on a secure server that is password protected, etc).

_____

18. Data Access - Indicate who will have access to these data in the future for this study.

_____

SECTION V: AGREEMENTS AND LIABILITIES

19. Agreements

19A. ***Contract/Research Agreement*** **-** Indicate whether there is a contract/research agreement involved between the researcher/s and a sponsor/research organization for this study.

___Yes ___No ___N/A

If yes, provide name of sponsor/research organization:

_____

19B. ***External Liability Insurance*** - Indicate if there is external (non-institutional) liability insurance.

___Yes ___No

19C. ***Medical Liability*** - Indicate who will cover reasonable out-of-pocket expenses to ensure that immediate medical care is provided if the participant suffers an injury as a result of participation in the study.

__Sponsor
__Institution
__Other (Specify):_____
__N/A

20. Publication Agreements

20A i. ***Indicate if there is an agreement between the investigator and the sponsor regarding the use, publication or disposal of data.***

___Yes ___No ___Pending

20A ii. ***If yes, indicate whether the funding agency or sponsoring company places any restrictions on publication of findings or reporting interim results.***

___Yes ___No ___Pending

20A iii. ***If yes, explain any restrictions.***

_____

SECTION VI: DECLARATION AND APPROVAL

PRINCIPAL INVESTIGATOR/CO-INVESTIGATORS/GRADUATE STUDENT DECLARATION

I/we certify that the information provided in this IRB Application Form is complete and accurate; assume full responsibility for the scientific and ethical conduct of the study as described in this application and submitted proposal; and agree to conduct this study in compliance with the USC's Standards for Responsible/Ethical Conduct for Research Involving Human Participants.

Signature of Principal Investigator/Graduate Student: _____Date:_____

Signature of Co-Investigator:_____Date:_____

Signature of Co-Investigator:_____Date:_____

SCHOOL/DEPARTMENT/ DIVISION/PROGRAM CHAIR/THESIS SUPERVISOR APPROVAL

I have reviewed and approved this proposal and support its submission for IRB review. I consider it to be feasible and appropriate.

Title: _____ First Name: _____ Last Name: _____

Signature of School/Dept/DIV/Program Chair/

Thesis Supervisor Signature: _____Date: _____

End of the Document

Revised October 18, 2016

Approved by APC: October 18, 2016