HAMPTON UNIVERSITY
INSTITUTIONAL REVIEW BOARD
IRB REVIEW APPLICATION

SECTION A: GENERAL INFORMATION

Project Title:

Principal Investigator:

Department:

School:

Address:

Telephone:

Email Address:

Is this project a continuation of a previously approved project?

Project Period:

Funding Source:

ADVISOR INFORMATION (For Student Research ONLY)

Faculty Advisor:

Faculty Advisor Address:

Faculty Advisor Telephone:

Faculty Advisor Email Address:

SECTION B: INTRODUCTION

(Includes background, rationale, statement of purpose, aims and objectives, research questions, or hypotheses. Include in-text and reference lists in this section as appropriate.)

Background

Rationale

Statement of Purpose

Aims and Objectives

Research Question(s)/Hypothesis (if applicable):

SECTION C: METHODOLOGY

Study Design: Give a brief overview of the design. Cite references on the proposed research methods as needed. If there is an intervention, include a section clearly describing the intervention involved. Are there any alternatives to the proposed (i.e. "experimental") procedure? If so, what are they?

Data Source: (Indicate as appropriate)
Primary data: This refers to data that is collected firsthand by a researcher or a team of researchers for a specific research purpose using data collection methods such as surveys, interviews, observations, and experiments
Secondary data: This refers to information that has been collected and or processed by someone else, rather than the investigator gathering the data firsthand. It involves the use of data from existing databases.

Primary Data (Yes/No): _____ **Secondary Data (Yes/No): _____**

If primary data (Select all that applies):
Survey (Yes/No): _____ Interviews (Yes/No): ____Focus Group (Yes/No): _____

Observations (Yes/No): _____ Experiment (Yes/No): _____ Case Studies (Yes/No): _____

Recording: Audiovisual (Yes/No): _____ Audio (Yes/No): _____ No recording: _____

If secondary data (Select all that applies):
Organizational data (Yes/No): _____ Public data (Yes/No): _____ Online data (Yes/No): _____

Historical data (Yes/No): _____ Private data (Yes/No): _____ National/International data (Yes/No): ____

Setting: Describe the location where the study will be conducted, including how you will plan to gain access to subjects in the setting and procedures for obtaining permission for the study. Attach any supportive documentation (i.e. letter of agreement from the host agency).

Participants: Include criteria to be used in selecting participants, including any inclusion or exclusion criteria (e.g. age, gender, and ethnicity). Give an anticipated number of subjects. Discuss criteria related to health status, if relevant. Provide any other additional information that may help to determine potential risk to participants.

Recruitment Procedures: Describe how participants will be recruited and selected. Describe the limitations and delimitations of the study. Attach any advertisements, flyers, consent forms, and verbal or written information given to potential subjects.

Sample Size and Sampling Technique: Describe how many participants you anticipate recruiting to enhance the validity of the study. Describe the sampling technique to be employed in this study and how it would enhance the validity of the study.

Instruments and Measurement/Data Collection Procedures: Describe measures, instruments, or tools to be used. Clearly describe the outcome and exposure variables and other covariates to be measured in this study AND the procedure for collecting the data (measurements). Attach copies of all data collection instruments. Describe the validity and reliability of instruments. Attach verification of the author's ***permission to utilize copyrighted material***. If ***secondary data*** is being collected in this study, describe the data source and if the data extraction includes any personal identifier.

Outcome Variable(s): Description and Measurement procedure

Exposure Variable(s): Description and Measurement procedure

Other covariates(s): Description and Measurement procedure

Data Analysis Plan: Describe how you would analyze the data obtained to answer the research question. Include the descriptive, inferential statistic methods and statistical package to be used. State the statistical significance level.

SECTION D: INFORMED CONSENT PROCESS

Informed Consent Procedure: How will you obtain informed consent from participants (and parents if applicable)? ***Describe the process*** of informing the participants about the study and the process of obtaining an informed consent.

Participants' Involvement: What will the participants be asked to do in the study? Describe, in detail, the tasks the participants would be required to do as part of their involvement in this study. This should include confidentiality, voluntary participation,

Does this study involve any of the following populations?
Children, minors, pregnant women, fetuses, human in vitro fertilization, prisoners, employees, military persons and students in hierarchical organizations, terminally ill, comatose, physically and intellectually challenged individuals, institutionalized or elderly individuals, visual or hearing impaired, ethnic minorities, refugees, and economically and educationally disabled individuals.

If yes, specify:

Inducement: Discuss any inducements, such as money or gifts, used for participation. If payments are given, discuss the amount and method of disbursement.

Transparency:

Are any aspects of this study kept secret from the participants?

Is any deception used in this study?

Are participants misled about any aspect of this study?

Will the participants be recorded on video or audio-taped?

Will the participants be recorded on video or audio-taped without their knowledge?

Risk/Benefit:
Discuss the potential risks of the study. This may include possible physical injury, complications or side effects, emotional distress, or violation of privacy.

What will you do to protect participants from these potential risks? ***Discuss how risks will be minimized or consequences handled***.

What benefits can reasonably be expected from the study? Discuss ***direct benefits to the individual***, if any, as well as to a ***particular community or society at large***.

Describe the processes to enhance the duty of care for participants ***in case of direct harm or injury as a result of participating in this study***. This may include but is not limited to the process of reporting, referral for treatment, or counseling.

What is the ***potential impact*** of the study on the ***subject, the institution, and the field***?

Confidentiality: ***<u>Describe (process) how</u>*** you will protect the confidentiality of the participants of this study.

Participants' Debriefing:

Will Participants be debriefed?

Informed Consent Checklist:

Please ensure the Informed Consent form addresses the areas listed below.

1	The purpose of the research is clearly stated	Yes or No (NA)
2	the time it will take the subject to participate in the study	
3	procedures to be followed and which procedures are experimental	
4	reasonably foreseeable risks or discomforts	
5	benefits to the subject or others	
6	alternative procedures for treatment	
7	confidentiality of records which identify the subject	
8	if more than minimal risk: availability of medical treatment in the case of research-related injury, including who will pay for the treatment and whether other financial compensation is available, if there is a potential for emotional/psychological risk, you must be able to provide proper counseling and indicate who will provide the counseling	
9	whom to contact for answers to pertinent questions about the research and the research subject's rights, and whom to contact in the event of a research-related injury	
10	participation is voluntary; refusal will involve no penalty or loss of benefits to which the subject is otherwise entitled	
11	risks to the subject (or the fetus or embryo if the subject is or may become pregnant)	
12	Are children, minors, pregnant women, fetuses, human in vitro fertilization, prisoners, employees, military persons and students in hierarchical organizations, terminally ill, comatose, physically and intellectually challenged individuals, institutionalized or elderly individuals, visually or hearing impaired, ethnic minorities, refugees, and economically and educationally disabled individuals involved in this study?	
13	participation may be terminated by the investigator without regard to the subject's consent; procedure(s) for termination	
14	cost of participation in the subject	
15	compensation to the subject	
16	significant findings will be provided to the subject upon request	
17	approximate number of subjects in the study	
18	right to have a copy of the consent form	

Important Note
Please use this checklist to ensure the Informed Consent Form addresses all areas listed.

SECTION E: DATA MANAGEMENT AND WORK PLAN

Study Administration, Monitoring, and Utilization of Results: ***<u>Describe (process) how</u>*** the data collection and entire study would be managed. Include a monitoring plan and how the data would be utilized and kept during and after the study.

WORK PLAN

(This is a template that can be modified as appropriate)

	Activities	**Year**											
		J	**F**	**M**	**A**	**M**	**J**	**J**	**A**	**S**	**O**	**N**	**D**
1	Proposal development												
2	Proposal submission for research & and ethics review	X	X										
3	Proposed Data Collection			X	X	X							
4	Data Cleaning & Analysis				X	X	X						
5	Report Writing							X	X	X			
6	Open forum presentation								X				
7	Draft Submission: Research Report									X			
8	Final Submission: Research Report										X		
9	Research Report sent to Research Office and Library.											X	
10	Research Summary for Stakeholder Information											X	

<u>Important Note</u>

Please make sure you attach all necessary documents required to make an informed decision about the approval of your study. This may include but is not limited to, copies of questionnaires, data collection instruments, copies of surveys, prior permission, collaboration letters, permission to use an instrument, etc.

SECTION F: REFERENCE LIST

SECTION G: APPENDICES